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HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987

HEARINGS

BEFORE THE

SUBCOMMITTEE ON LABOR

OF THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

FIRST SESSION

ON

S. 79

TO NOTIFY WORKERS WHO ARE AT RISK OF OCCUPATIONAL DISEASE IN ORDER TO ESTABLISH A SYSTEM FOR IDENTIFYING AND PREVENTING ILLNESS AND DEATH OF SUCH WORKERS, AND FOR OTHER PURPOSES

FEBRUARY 24, 1987

PART 1

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CONTENTS

STATEMENTS

Tuesday, February 24, 1987

Page

American Association of Nurserymen, Inc., prepared statement 213
American Association of Occupational Health Nurses, prepared statement 255
American Council on Education, prepared statement 299
American Industrial Hygiene Association, prepared statement 301
American Subcontractors Association, prepared statement 286
American Wood Preservers Institute, prepared statement 252
Associated Builders & Contractors, Inc., prepared statement 273
Cheek, Leslie, Senior Vice President of Federal Affairs, Crum & Forster Insurance Cos.'; Robert E. Finnigan, Chairman, Environmental and Occupational Health Operating Committee, American Electronics Association; Robert Clark, National Tooling and Machining Association; and Tom Evans, National Association of Manufacturers 144
  Prepared statement of:
    Mr. Cheek 147
    Mr. Finnigan 171
    Mr. Clark 184
    Mr. Evans 196
Hatch, Hon. Orrin, a U.S. Senator from the State of Utah, prepared statement 7
Humphrey, Hon. Gordon J., a U.S. Senator from the State of New Hampshire 3
Landrigan, Dr. Philip J., President, Association of University Programs in Occupational Health and Safety; Dr. John Seffrin, Vice President, National Board of Directors, the American Cancer Society, and Dr. James A. Merchant, on behalf of the American Lung Association and the American Thoracic Society 8
  Prepared statement of:
    Dr. Landrigan (with attachments) 11
    Dr. Seffrin 47
    Dr. Merchant (with attachments) 62
National Association of Independent Insurers, prepared statement 246
National Association of Wholesaler-Distributors, prepared statement 219
National Stone Association, prepared statement 260
Rubber Manufacturers Association, prepared statement 244
Samuel, Howard D., President, Industrial Union Department, AFL-CIO, accompanied by David Mallino, Legislative Director; Margaret Seminario, Associate Director, Department of Occupational Safety, Health and Social Security, AFL-CIO; Robert Watson, Recording Secretary, USWA Local 1066, Gary, IN, and George Cafasso, Safety and Health Committee Chairman, USWA Local 1557, Clairton, PA 123
  Prepared statement of:
    Mr. Samuel 125
    Mr. Wright 136
Standard Oil Co., prepared statement 277
Tenneco Inc., prepared statement 269
Windom, Dr. Robert, Assistant Secretary for Health, Department of Health and Human Services, accompanied by Dr. James Melius, Director, Division of Surveillance, Hazard Evaluations and Field Studies, National Institute for Occupational Safety and Health; and Dr. J. Donald Millar, Director, National Institute for Occupational Safety and Health 87
  Prepared statement 90

ADDITIONAL MATERIAL

Articles, publications, etc.:

Page

- Section-by-section analysis of S. 79, direct annual costs and personnel needs for DHHS 100
- List of people that have contracted lungs, throat, or respiratory cancer from United Steelworkers of America 142
- National Registry proposal, Agency for Toxic Substances and Disease Registry, January 1987 312

Questions and answers:

- Responses to questions submitted by Senator Hatch of:
  - Dr. Landrigan 19
  - Dr. Seffrin 55
  - Dr. Merchant 76
  - Dr. Windom 119

HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987

TUESDAY, FEBRUARY 24, 1987

U.S. Senate,
Subcommittee on Labor,
Committee on Labor and Human Resources,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room SD-430, Dirksen Senate Office Building, Senator Howard Metzenbaum (chairman of the subcommittee) presiding.

Present: Senators Metzenbaum, Hatch, Quayle, Stafford, Harkin, and Matsunaga.

OPENING STATEMENT OF SENATOR METZENBAUM

Senator Metzenbaum. The Committee will come to order. It is my understanding that several of our colleagues expect to join us, and we will welcome them when they arrive.

Today's hearing addresses S. 79, the High Risk Occupational Disease Notification and Prevention Act of 1987.

Occupational disease is one of our nation's major health problems. Each year, between 50,000 and 100,000 Americans die from diseases caused by on-the-job exposure to toxic chemicals, wastes, fumes, dusts or industrial processes. That is more American lives lost each year than were lost either in Vietnam or in Korea. It is shameful, and it need not be.

In fact, more Americans have died from occupational disease in this country in the past 40 years than in all our wars dating back to 1776. When you add in the hundreds of thousands of workers who are disabled annually from occupational disease, it is clear that we are failing in the battle to preserve occupational health. The consequences of this failure are enormous. The resultant health care costs to families, to government, to employers, run into the hundreds of millions of dollars. The cost in terms of human misery cannot be measured.

It does not have to happen.

Occupational diseases are very often preventable. The worker populations involved can be identified in relatively precise terms. The hazards to which they are exposed can be enumerated and measured. And the occurrence of disease can be minimized through early medical screening and health counseling.

Sadly, the Reagan Administration has turned its back on the occupational health crisis. NIOSH, the Federal agency responsible for identifying occupational hazards and recommending ways to control them, has had its budget cut 38 percent in real dollar terms since 1981.

OSHA has virtually ceased issuing workplace health regulations over the past six years. Its one notable accomplishment, the Hazard Communication Standard, applies only to manufacturing industries. Millions of workers are not covered at all, and even in manufacturing, there are significant problems of noncompliance.

After six years of Federal neglect, this nation needs an occupational health defense initiative.

Senate Bill 79, which Senator Stafford and I introduced, and I am pleased to say that we now have 23 cosponsors, is a first step in that direction. The working men and women of this country have a right to know—a right to know—if their jobs create a high risk that they will contract a life-threatening disease. And those who are at risk should have a right to advice on how to obtain appropriate medical monitoring.

Senate Bill 79 endows workers with these simple, yet life-saving rights. The proposed legislation establishes a low-cost system for identifying, notifying and monitoring at-risk worker populations.

By undertaking such a national detection and prevention effort, we will reap three enormous benefits. First, for thousands of workers and their families, we will avoid the misery of death or disabling disease. Second, through prevention or successful treatment, we will save millions of dollars in health care costs. Finally, we will serve the ends of simple justice.

Congressman Gaydos first introduced an occupational disease notification bill in the House in 1985. Since that time, there have been six hearings in the House and Senate on this legislation. S. 79 includes many changes from the original House bill, changes intended to make this legislation fair and workable for all affected parties.

We have altered the definition of "risk" to conform to the approach already in use under the Reagan Administration's own Hazard Communication Standard.

We have inserted procedural protections to ensure that the notification process includes a public hearing and the right to judicial review.

We have added provisions minimizing any exposure to liability arising out of the notification process.

These are important issues. If more needs to be done in these areas, we will do more. We are prepared to make other changes in order to fashion the best law possible. Our doors are open to working with the business community, the Administration, and all other interested parties to fashion a bill that is fair to all parties concerned.

This morning we will be listening to testimony from opponents as well as supporters of S. 79. I welcome both sides, because I believe that we need constructive criticism in order to produce a bill that is fair to employers as well as workers, and one that can be enforced effectively by the Administration.

But two points should be made clear. First, it is too late in the day to deny the need for such a law. The issue is what form it should take. That issue requires answering a number of complex technical questions, and it is high-time that we do so.

Second, we will be reporting S. 79 to the Floor later this year. For those in the Administration and the business community, now is the time to work with us to improve the bill. We do not claim that it is perfect. We are prepared to work with all those interested. As is clear from our track record, we have made changes, we have made modifications, and we will in the future listen carefully to those who have something constructive to offer.

I say to those who are concerned about this legislation, this is your chance to show that you, too, want to address one of our nation's most pressing health problems.

At this point me will receive for the record a statement by Senator Humphrey.

[The prepared statement of Senator Humphrey follows:]

STATEMENT OF HON. GORDON J. HUMPHREY, A U.S. SENATOR FROM THE STATE OF NEW HAMPSHIRE

Senator **Humphrey**. Since the inception of the Occupational Safety and Health Administration in 1970 and the Mine Safety and Health Administration in 1977, the Department of Labor has spent over $2 billion in promulgating and enforcing Federal health standards—standards designed to reduce worker exposure to harmful workplace agents. Over 20 such standards affecting millions of workers are on the books; additional standards are in the proposal stages.

S. 79 proposes that the Federal Government take upon itself an additional notification burden—a scheme requiring the Health and Human Services Department to notify at least 100,000 and perhaps as many as 300,000 workers per year. This notification is based on vague and questionable scientific standards.

One of my real objections to this proposal is that it adds yet another layer of Government on top of the existing agencies created to deal with workplace safety. I don't see how everything this legislation requires can be accomplished for the authorized funding level of $25 million dollars either. A more realistic estimate would be something on the order of $250 million. I suspect that we have the makings of another Black Lung Program.

The proposal does nothing to solve one of the most pressing health problems confronting today's workers—smoking in the workplace. Studies show that smoking greatly enhances the risk of acquiring a disease commonly related to workplace exposure. I suggest that the Labor Subcommittee would better serve workplace safety by focusing on the hazards of smoking, for example.

The purpose of this legislation is to increase employer liabilities for past exposure problems. Consequently, employers' health and safety budgets will be redirected from dealing with current threats to employee health to dealing with greater liability claims for past practices.

Mr. Chairman, while I certainly support efforts to protect our workers, I am very concerned about the scope of this particular legislation: it is duplicative; it will be very costly; and its ultimate impact is unclear.

Senator **Metzenbaum**. I am very happy to welcome this morning the Ranking Minority Member, Senator Hatch, and Senator

Quayle. I am happy to have you both with us this morning. If you have an opening statement, I would be very pleased to hear from you at the present time.

OPENING STATEMENT OF SENATOR QUAYLE

Senator **Quayle**. Well, thank you, Mr. Chairman.

First of all let me take this opportunity to commend you for introducing legislation on the subject of risk notification and calling this hearing. I think you are right on target in your statement that what we need to discuss is what form the legislation should take.

I do not think there is any dispute, that when the Federal government has certain knowledge relevant to the health of specific individuals, it is certainly the government's obligation to inform that individual of this information.

In my view, your bill addresses a very important public health problem, and that is what to do about notifying individuals of their risk of contracting an occupational disease as a result of their exposure to a hazardous substance.

However, Mr. Chairman, I believe that S.79 as presently drafted goes far beyond that basic ethical principle, and I think that it is necessary to develop a more flexible and scientifically sound approach to notification. And as you know, I am in the process of developing an alternative approach which I intend to introduce in the near future.

In brief, my approach would require that ethical standards be developed to deal with the question of notification for the subjects of epidemiological record studies which indicate that the subjects are at risk of contracting a disease as a result of their exposure to hazardous substances or physical agents. It would also require that such standards be developed to address the question of notification to populations beyond the studied subjects, in instances where extrapolation of study results is deemed to be scientifically valid.

Under my approach, the actual application of these ethical standards which would trigger notification—I believe that is absolutely key—would be made through the scientific peer review process.

The Federal government already has in place, widely respected standards concerning the ethical protection of human subjects of biomedical and behavioral research. However, epidemiological studies are not generally covered by these standards because they do not involve direct contact with the subjects and any procedural medical risks.

The main purpose of my proposal is to require the development of ethical standards to deal with the types and contents of notifications to populations which are at risk as a result of their exposure to a hazardous substance or physical agents and under what circumstances and conditions those populations should be notified.

In addition, my proposal is designed to wall off the liability issue because I believe that what we have at stake here is a matter of determining the appropriate health policy for individuals believed to be at risk.

I certainly look forward to the testimony of our distinguished witnesses today and note that two of our witnesses will be from the great Hoosier State of Indiana. I am certain I will find this hearing useful both in evaluating our Chairman's proposal and in refining my own view of this very important issue.

I would also like to note that the Chairman has very graciously consented to my request for an additional day of hearings, to be held on March the 9th, to accommodate the many diverse groups who will be affected by this legislation.

Thank you, Mr. Chairman.

Senator METZENBAUM. Thank you, Senator Quayle.

Senator Hatch, we are happy to have you with us this morning.

OPENING STATEMENT OF SENATOR HATCH

Senator HATCH. It is nice to be here, Senator Metzenbaum.

Mr. Chairman, we appreciate having the opportunity to be here and listen to the witnesses who are going to testify here today.

I think this is an extremely important topic, when and how to inform American workers about exposures to hazardous substances.

There seems to be a consensus on this Committee that a worker who has been exposed to a hazardous substance should be informed of that fact when successful medical intervention is available.

Unfortunately, the implementation of this simple principle leads to a number of complicated questions. Some of these questions include: How much and what type of scientific evidence should provide the basis for identifying a substance as an occupational health hazard, and who should make that decision? Which workers should be notified, and how should those workers be notified? Who should pay for the notification, and who should pay for the follow-up medical care? What responsibilities do workers have for actions which may increase their exposure to risks, actions such as smoking, alcohol use, obesity, et cetera?

We have seen, for instance, in the radiation compensation hearings that we held that in some of the uranium miner situations, those who smoked had a higher incidence of health difficulty. Now, what responsibilities do the workers have. And what effect should notification have on liability? That is not an inconsequential question.

I come from a State where our steel industry is down, our copper industry has been down, our mineral industry in one of the greatest mining States in the world is down, our oil and gas industry is down. In fact, almost anything that smacks of development is down. One reason is we have placed so many rules and restrictions and costs on business back here in Washington that it is almost impossible to have jobs in some of these very critical areas.

It is happening throughout heavy industry, everywhere in our country today. We are losing our heavy industry and becoming just a service-oriented economy. That is a very serious problem, and it is caused by solving these problems with all-embrasive legislation, then when we get through with our legislation, the bureaucracy comes up with a myriad of regulations. The end result is a solution which does not really help in the real world.

I am concerned about just what the real world response should be in this particular area, as we worry about workers and as we worry about the problems they face. And I am worried about jobs, too. I am worried about whether or not we are going to keep people working, with more and more regulation from Washington.

This is an important problem, and I think it is important that we carefully analyze possible answers to all of these questions. We have to act wisely. I do not think we should squander our efforts and resources on extensive notification of workers who are at little or no risk when medical science can do nothing to reduce that risk. We have to acknowledge that.

Instead, we should focus our resources on preventing exposure, educating workers about the steps they can take to improve their own health and safety, and helping those who have been exposed to real occupational health risks. That is what we ought to be doing. We have to maximize our efforts and minimize the costs or we are not going to have any jobs in America. We are not going to have the ability to be competitive with the rest of the world.

So let us do what is right here, I will certainly be supportive of that. At a time when America is struggling to be more competitive, the last thing we want is to place a large burden on American business without a payoff in the form of improved health for American workers. If we do not get that payoff, then all the regulation in the world is not going to help.

I hope this series of hearings will provide carefully considered answers to some of these questions that I have raised. There are others. I know that members of this body are working to answer these questions. Senator Metzenbaum has introduced one piece of legislation; Senator Quayle is circulating proposed language for another, and before we are through, still other proposals will certainly surface. Then we have to go through the amendment process.

I look forward to hearing the testimony today, and working with both Senator Quayle and Senator Metzenbaum, when legislation reaches the Full Committee level.

I want to commend you, Mr. Chairman, for holding these hearings, and you, Senator Quayle, for the work that you are doing in this area, and I hope that we can resolve this in a way that will work for the benefit of everybody.

Senator METZENBAUM. Thank you, Senator Hatch.

[The prepared statement of Senator Hatch follows:]

From the office of

SEN. ORRIN HATCH

Washington, D.C. 20510

The High Risk Occupational Disease Notification and Prevention Act of 1987
February 24, 1987

We are here today to address an important topic -- when and how to inform American workers about exposure to hazardous substances.

There seems to be a consensus in this Committee that a worker who has been exposed to a hazardous substance should be informed of that fact when successful medical intervention is available. Unfortunately, the implementation of this simple principle leads to a number of complicated questions. Some of these questions include:

How much and what type of scientific evidence should provide the basis for identifying a substance as an occupational health hazard and who should make that decision?

Which workers should be notified and how should those workers be notified?

Who should pay for notification and who should pay for the follow up medical care?

What responsibilities do workers have for actions which may increase their exposure risks such as smoking, alcohol use, and obesity?

And, what effect should notification have on liability?

It is important that we carefully analyze possible answers to these questions. We must act wisely. We must not squander our efforts and resources on extensive notification of workers who are at little or no risk, when medical science can do nothing to reduce that risk. Instead, we should focus our resources on preventing exposure, educating workers about the steps they can take to improve their own health, and helping those who have been exposed to a real occupational health risk.

At a time when America is struggling to become more competitive, the last thing we want is to place a large burden on American business, without a payoff in the form of improved health for American workers.

I hope this series of hearings will provide carefully considered answers to some of these questions. I know members of this body are working to answer them. Senator Metzenbaum has introduced one piece of legislation, Senator Quayle is circulating proposed language for another, and before we are through, still others proposals will certainly surface.

I look forward to hearing the testimony today and working with both Senator Quayle and Senator Metzenbaum when legislation reaches the full Committee level.

Senator METZENBAUM. Our first witnesses today are Dr. Philip J. Landrigan, President, Association of University Programs in Occupational Health and Safety; Dr. John Seffrin, representing The American Cancer Society; and Dr. James A. Merchant, representing the American Lung Association and the American Thoracic Society.

I think the panelists have all been advised that we will use our usual rule and ask them to confine their remarks to five minutes, that their entire statements will be included in the record.

Senator QUAYLE. Mr. Chairman, could I make a special welcome to Dr. Seffrin, who is the Chairman of the Department of Applied Science at IU in Bloomington. I welcome him before the Subcommittee and especially look forward to his testimony.

Dr. SEFFRIN. Thank you, Senator.

Senator METZENBAUM. You can do that if you promise to listen carefully to his testimony.

Senator QUAYLE. I am going to listen very, very carefully, and I hope that you do likewise. [Laughter.]

Senator METZENBAUM. Dr. Landrigan, would you proceed, please?

STATEMENT OF DR. PHILIP J. LANDRIGAN, PRESIDENT, ASSOCIATION OF UNIVERSITY PROGRAMS IN OCCUPATIONAL HEALTH AND SAFETY; DR. JOHN SEFFRIN, VICE PRESIDENT, NATIONAL BOARD OF DIRECTORS, THE AMERICAN CANCER SOCIETY, AND DR. JAMES A. MERCHANT, ON BEHALF OF THE AMERICAN LUNG ASSOCIATION AND THE AMERICAN THORACIC SOCIETY

Dr. LANDRIGAN. Thank you, Mr. Chairman.

My name is Dr. Philip Landrigan. I am Director of the Division of Environmental and Occupational Medicine at Mount Sinai School of Medicine in New York. I have been there since 1985. Previously I was a Commissioned Officer in the U.S. Public Health Service for 15 years; for six years, 1979 to 1985, I was stationed in Cincinnati, where I was Director of NIOSH's Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH's largest division, the division that is responsible for most of the epidemiologic field work which is conducted by NIOSH, and the division which developed much of the ethical and scientific background that led to these hearings today.

I am also President of the Association of University Programs in Occupational Safety and Health. This is a national organization that represents the 14 Educational Resource Centers throughout the United States, which are supported by NIOSH and which are the nation's principal resource for training professionals in occupational health.

I appreciate your having asked me to testify before you today. I am appearing both on my own account, and also I represent the Association of University Programs, which overwhelmingly supports this bill.

There are several points in the bill on which I would like to comment. First of all, this is a very important bill. As professionals in occupational health, I and my colleagues in the Association of University Programs would like to make the point that the information which is provided to workers through this bill is going to be vital in enabling workers across the United States to take steps to protect their health and to obtain needed medical care.

Early notification and medical examination of workers occupationally exposed to hazardous substances will provide opportunities for disease prevention, for health education, and for medical intervention at an early stage in the course of occupational disease when treatment and cure may still be possible.

This approach is clearly the most efficient and the most cost-effective approach to the care and treatment of people who have already been exposed to hazardous substances in the workplace and who are suffering work-related illness.

With regard to criteria for notification, there will certainly be much discussion on this point, and clearly, the evolution of these bills from last year indicates that you, too, have reflected long and hard upon the issue of triggers for notification.

I find that the criterion of a statistically significant excess in mortality or in disease is a generally reasonable one. I disagree strenuously with the statement of the National Association of Manufacturers that this constitutes a "loose" test or a "loose" trigger. It is a tightly reasoned trigger which is based on state-of-the-art scientific reasoning. Of course, there may be special circumstances in which excess will not be an adequate criterion for trigger or when an excess may be spurious. The use of statistical tests is intended to minimize that eventuality, but it can still occur.

However, because the bill provides for the establishment of an Expert Board which will make final decisions concerning notification in the light of their collective professional experience, the bill contains the necessary safeguards to deal with such problems.

I have reviewed in detail the procedures that will be utilized by the Public Health Service pursuant to S. 79 for the notification of workers at high risk. A particularly difficult task here will be the location and notification of workers who are not themselves members of cohort populations that have been examined by the Federal agencies.

However, it is my opinion after having worked for 15 years in the Public Health Service and 6 of those at NIOSH, that it will be possible, so long as sufficient resources are provided, to use modern computer-based techniques to identify and notify such workers. A most important resource here is the National Occupational Exposure Survey and the data from the National Occupational Hazard Survey, which have been conducted by NIOSH and which identify occupational exposures across the United States—so-called "potential occupational exposures". It is possible through computer linkage to link those files with commercial files that indicate manufacturers such as the Dunn and Bradstreet file, to indicate which firms across the country are at risk of exposing their workers to hazardous substances. Such computer linking has been done by NIOSH, it has been done by UCLA, it has been done by our group at Mount Sinai. It is eminently feasible.

Another very important aspect of this bill is the provision it makes for medical follow-up. I have reviewed the costs of medical evaluation that might be involved in examinations of exposed workers, and I present a table on page 4 of my testimony that gives a few of these. I have more data as well, should you wish them.

Not all of these tests would be applied to every worker. You will see, however, that the overall costs here are not huge; these are based on actual costs of screening programs which have been run by our group at Mount Sinai Hospital in New York City.

Much criticism will be made of this bill from the point of view that it is redundant, that it reduplicates existing regulation and legislation. In particular you will no doubt hear testimony as you did last year that the so-called Hazard Communication Standard of the Occupational Safety and Health Administration will fulfill most of the tasks that S. 79 is intended to fulfill.

I would like to put it clearly before you that in my opinion that statement is inaccurate. I spell out in detail on page 5 of my testimony a number of reasons why the OSHA Hazard Communication Standard simply will not do the job.

You will hear today from the Administration that they are in the process of revising that standard to accomplish the needed goals. That is, I suppose, all well and good. But the standard as it exists today does not do the job, and S. 79 does, and therefore, S. 79 is hardly redundant; rather, it complements the standard, which is good, but only good so far as it goes.

So in conclusion, I and the Association of University Programs in Occupational Health and Safety strongly endorse S. 79. It is legislation which is necessary; it is legislation which is overdue; it is legislation which will provide a humane, scientifically sound and cost-effective approach to the problem of prevention of occupational disease in the United States.

Senator METZENBAUM. Thank you, Dr. Landrigan.

[The prepared statement of Dr. Landrigan with attachments and response to questions submitted by Senator Hatch follow:]

Association of University Programs in Occupational Health & Safety

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Raymond R. Suskind, M.D.
Past President, 1981-1982

Don B. Chaffin, Ph.D.
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Morton Corn, Ph.D.
Past President, 1983-84

Robert C. Spear, Ph.D.
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Jeffrey S. Lee, Ph.D.
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on S.79
The High Risk Occupational Disease Notification
and Prevention Act of 1987

Before the
Subcommittee on Labor and Human Resources
United States Senate

February 24, 1987

Philip J. Landrigan, M.D.

Mr. Chairman and Members of the Subcommittee.

My name is Philip J. Landrigan, M.D. I am Director of the Division of Environmental and Occupational Medicine and Professor of Community Medicine at the Mount Sinai School of Medicine of The City University of New York. Previously I was a Commissioned Officer in the United States Public Health Service. From May, 1979 until June, 1985, I was Director of the Division of Surveillance, Hazard Evaluations and Field Studies of the National Institute for Occupational Safety and Health (NIOSH), and in that capacity I had overall responsibility for a major portion of NIOSH's activities in the field of occupational disease epidemiology. I am President of the Association of University Programs in Occupational Safety and Health, the national organization representing the nation's 14 Educational Resource Centers in occupational health. These centers are supported by the National Institute for Occupational Safety and Health, and they represent the nation's principal educational resource in occupational medicine, occupational health nursing, industrial hygiene and safety engineering. A copy of my curriculum vitae is attached to my testimony.

Thank you for having invited me to testify before you on S. 79, the High Risk Occupational Disease Notification and Prevention Act of 1987. I am pleased to do so. I shall be testifying both as an individual and also in my official capacity as President of the Association of University Programs in Occupational Health and Safety.

Importance of This Bill for Prevention of Occupational Disease

I should like to begin by expressing my strong personal support and the overwhelming support of the Association of University Programs in Occupational Health and Safety for this bill. The bill is realistic, and it is practical. The bill will accomplish very important objectives in the field of occupational medicine, in that it will provide workers with vital information about their health status. This information will enable workers across the United States to take steps to protect their health and to obtain needed medical care. Early notification and medical examination of workers occupationally exposed to hazardous substances will provide opportunities for disease prevention, health education and medical intervention at an early stage in the course of work-related illness, when treatment and cure may still be possible. Such early intervention is the most efficient and cost-effective approach to the care and treatment of persons with work-related illness.

Criteria for Notification

I have reviewed in detail the criteria which have been established in the Bill for the identification of populations at high risk. I find that the criterion of a statistically significant excess in mortality is a generally reasonable one. There may be special circumstances in which such an excess will not be an adequate criterion to trigger the notification of workers at high risk, either because a particular epidemiologic study has not been adequately conducted, or because there are certain peculiarities surrounding a particular case. However, because the Bill provides for the establishment of an Expert Board, which will make final decisions concerning notification (after opportunity for Public Hearing and comment), the Bill thereby contains the necessary mechanism to deal with such problems.

Procedures for Notification

I have reviewed the procedures which will be utilized by the U.S. Public Health Service for notifying workers at high risk, pursuant to S.79. A particularly difficult task will be the location and notification of workers who are not themselves members of cohort populations which have been directly studied by federal agencies.

Although the task of notification of such workers will not be easy, it nevertheless can be accomplished with relative efficiency using modern computer-based techniques for data handling and record linkage. A most important resource in this endeavor will be the computerized data base established by NIOSH in its National Occupational Exposure Survey and its National Occupational Hazard Survey. This enormous file identifies those categories of workers (by occupation and industry) in the United States who are potentially exposed to hazardous substances. Information from that data base can be cross-linked (using the Census Bureau's Standard Industrial Classification [SIC] codes) with commercial data bases, such as the Dun and Bradstreet file. Such cross-linking, which has been undertaken previously by NIOSH as well as by our group at the Mount Sinai School of Medicine and a group at the University of California at Los Angeles makes it possible to identify individual firms with potentially hazardous exposures. That information can be further refined by correlation with data from the Occupational Safety and Health Administration's (OSHA) Management Information System. The OSHA files, all of which are also computerized and coded by the same codes as the NIOSH file, indicate those firms in which workers have actually been exposed to hazardous substances at concentrations above OSHA action levels.

The above procedures can be efficiently accomplished, and in fact they have been accomplished previously. With adequate allocation of manpower and resources it is well within the capability of the U.S. Public Health Service to undertake the identification of workers who have been occupationally exposed to carcinogens and other hazardous substances in workplaces throughout the United States.

Importance of Medical Surveillance

One of the most important aspects of S.79 is its provision of resources for medical follow-up of workers exposed to hazardous substances. This is an extremely important provision. Simple notification of workers that they are at high risk of occupational disease does little by itself to prevent illness. Notification must be viewed as the first step in a complex process. The second step is medical evaluation. Further, one-time medical evaluation is not enough, inasmuch as many occupational diseases become medically evident only after many silent years of latency. Therefore, an initial medical examination must be succeeded by additional follow-up examinations.

I have reviewed the costs of medical evaluation such as might be involved in examinations of exposed workers. They are presented in the following table. Actual costs in a particular case will vary with the particular array of tests performed. Not all of these tests will need to be performed in all instances, and additional tests may in some cases be required.

Procedures		Costs
Medical examination by a physician	-	$ 100.00
Chest X-ray	-	45.00
Pulmonary function testing	-	38.00
Complete blood count	-	10.00
Serum chemistry screen	-	25.00
Urinalysis	-	6.00

It is evident that these costs are not massive. Further, economies of scale may result if large numbers of workers are screened at one time.

Previous Criticisms of the Bill

Several witnesses at Hearings held in 1986 on H.R.1309 and S.2050, earlier versions of the present legislation, offered a variety of criticisms of the Bill. I should like to comment on those points.

First, it is important to note that almost without exception the various witnesses who appeared last year before this Subcommittee and its House counterpart stated that they supported the principles underlying the High-Risk Worker Notification Bill. That, in my opinion, is an important step in the right direction. This unanimity of support indicates general recognition of the ethical and medical necessity of informing workers about their work-related health risks.

Several witnesses last year, among them Mr. Patrick R. Tyson, then the Acting Assistant Secretary of Labor for Occupational Safety and Health, stated that the OSHA Hazard Communication Standard (29 CFR 1910.1200) would accomplish the goals of the proposed Bill. That statement is seriously inaccurate in several respects. First of all, the OSHA Hazard Communication Standard pertains to the notification of only current and future workers. By contrast, S.79 aims at providing information to all exposed workers - past, present and future. Secondly, the Hazard Communication Standard is intended to provide workers with information pertaining to the chemical nature and hazards of the substances with which they work; as far as it goes, that is a laudable goal. By contrast, however, S.79 is intended to provide workers with information pertaining to their personal health status and health risks, in addition to information concerning chemical hazards. Further, it makes provision for medical surveillance of exposed workers. Thirdly, major categories of workers are excluded from the OSHA Hazard Communication Standard, as it now stands. These excluded groups of workers include:

- Workers who have retired, or are disabled.
- Workers laid off at plants that have been permanently shut down.
- Workers who have changed jobs, and who are no longer employed by the firm at which exposures took place.
- Farm workers and workers in small businesses not covered by OSHA enforcement and compliance programs.
- Workers employed by state and local governments who are not covered by State OSHA plans.

All of these categories of workers would be covered by S.79.

For all of the above reasons then, the statement by the Administration that the OSHA Hazard Communication Standard will accomplish the aims of S.79 is simply not accurate and should be disregarded.

Mr. Tyson also noted last year that under Section 6(b) of the Occupational Safety and Health Act workers must be notified of the results of medical examinations conducted under all specific OSHA Health Standards issued since 1974. This statement is correct. However, to put the statement in perspective, it must be noted that only eight OSHA Standards mandate specific medical examinations. These eight standards are: arsenic, lead, coke oven emissions, acrylonitrile, vinyl chloride, cotton dust, ethylene oxide, and dibromochloropropane (DBCP). These eight materials comprise only 0.016 per cent of the 50,000 chemical substances currently registered with the Environmental Protection Agency's Office of Toxic Substances. Thus, for workers exposed to the remaining 99.984

per cent of chemical compounds in use in the United States, Section 6(b) of the OSHA Act is not relevant.

Mr. Tyson also stated last year that since August, 1980, "OSHA regulations have required employers to inform their current and former employees of the existence, location and availability of exposure records maintained by the employer in connection with each employee, and to inform current and former employees of their right of access to such records". However, as Dr. John Finklea, former Director of the National Institute for Occupational Safety and Health and now Professor of Occupational Medicine at the University of Alabama, noted in his testimony last year, this aspect of the OSHA Act has simply not been enforced, and it has not been an effective mechanism for conveying health information to workers. Dr. Finklea noted "that many workers are not covered by OSHA Compliance Programs and, therefore, are not guaranteed access to relevant records. Even for workers covered by the OSHA Standard dealing with access to employee exposure and medical records, accessibility is not a matter of routine. Where there are well established occupational safety and health programs with appropriate corporate policy support, adequate professional staffing and strong worker participation, worker access to medical and exposure records may no longer be a problem. Unfortunately, many work sites do not have that kind of occupational safety and health program. In these cases, access is made difficult."

Dr. William Gaffey of the National Association of Manufacturers argued last year that the trigger for worker notification in the High-Risk Worker Notification Bill would ignore statistical variation in mortality. Dr. Gaffey's point has some validity, and it reflects an issue which surrounds every diagnostic procedure in medicine. No diagnostic test is absolute; all diagnostic tests seek to evaluate statistical variation from the norm. Physicians, epidemiologists and statisticians have, however, well developed procedures for assessing this variation, and those procedures are applied every day in medicine. Evaluation of test results to determine whether or not they are "statistically significant" is the cornerstone of this evaluative process. The designation in S.79 of a statistically significant excess in mortality as the criterion for notification indicates recognition of and sensitivity to this issue. Further, any unresolved questions will be addressed on a case-by-case basis by the expert Review Board to be established by S.79. It will be the responsibility of the Board (after Public Hearing) to sort out issues of true variation from those of statistical fluctuation.

Finally, I must disagree strenuously with the position taken last year by the National Association of Manufacturers that the High-Risk Worker Notification Bill is "redundant and unnecessary." As I have stated, this Bill will provide information to workers which complements the information which is provided under the OSHA Hazard Communication Standard and under Section 6(b) of the OSHA Act. Additionally, however, the Bill will provide information which is available to workers from no other source, and which is essential for the protection of health.

Conclusion

In conclusion, I strongly endorse S.79. It is legislation which is necessary. It is legislation which is overdue. It is legislation which will provide a humane, medically sound and cost-effective approach to the problem of occupational disease prevention in the United States. Speaking both for myself and for the Association of University Programs in Occupational Health and Safety, I urge passage of this legislation.

PJL:ss

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March 11, 1987

The Honorable Howard Metzenbaum
Chairman, Subcommittee on Labor
Committee on Labor and Human Resources
United States Senate
Washington, DC 20510-6175

Dear Senator Metzenbaum:

Thank you very much for having sent me the additional questions from Senator Orrin C. Hatch pertaining to S.79, the High Risk Occupational Disease Notification and Prevention Act. I am pleased to respond to these questions and to elaborate on several of the points which I made in my testimony.

1. The most comprehensive American list of the known occupational diseases is contained in the text Environmental and Occupational Medicine by William N. Rom, M.D. Dr. Rom trained in occupational medicine in our residency program at the Mount Sinai School of Medicine. He subsequently served on the faculty at the University of Utah. He wrote this encyclopedic textbook while at Utah. Further, I understand that Dr. Rom had the privilege to make the acquaintance of Senator Hatch during those years. Dr. Rom informs me that he arranged for a presentation copy of his text to be presented to Senator Hatch in late 1983.

   Medical intervention subsequent to exposure is effective for the treatment or alleviation of symptoms of many, although not all, occupational diseases. Further, it is almost axiomatic that such intervention is more effective if undertaken early, rather than late. The following is a partial list of occupational diseases for which medical intervention is effective:

Condition		Form of Treatment
Lead Poisoning.	-	Chelation therapy and removal from exposure.
Mercury Poisoning.	-	Chelation therapy and removal from exposure.
Silicosis.	-	Reduction in exposure, smoking cessation, supportive pulmonary therapy.
Asbestosis.	-	Reduction in exposure, smoking cessation, supportive pulmonary therapy.
Coalworkers' Pneumoconiosis.	-	Reduction in exposure, smoking cessation, supportive pulmonary therapy.
Cancer of the Bladder.	-	Cystoscopy and early surgery.
Cancer of the Colon.	-	Colonoscopy and early surgery.
Cancer of the Nasal Sinuses.	-	Early surgery and radiotherapy.
Peripheral Neurologic Disease.	-	Cessation of exposure and physiotheraphy.
Anthrax.	-	Rapid antibiotic therapy.
Tuberculosis.	-	Antibiotic therapy.
Skin Cancer.	-	Early surgery.
Pesticide Poisoning.	-	Removal from exposure and specific antidotes, such as PAM.

An added benefit of notification of workers in an exposed population is that various workers in such populations may be expected to be at differing stages in the evolution of their occupational illness. Thus, some workers may unfortunately already be at a point at which medical intervention is not likely to be very efficacious. Others, however, benefit from the unhappy experience of the first group, and in these workers early detection of disease followed by prompt medical intervention can prevent disease disability and death.

Smoking cessation, in some instances, is part of the total medical management of workers who have been exposed to occupational toxins. Such is the case in virtually any of the occupational pulmonary diseases, such as silicosis, asbestosis, coalworkers' pneumoconiosis, or byssinosis; cigarette smoking by itself does not cause any of these diseases, but can aggravate the symptoms.

There are, however, many occupational diseases which are entirely unrelated to smoking. Although smoking cessation is clearly a laudable goal in all persons, it is of neither positive nor negative benefit in the medical management of such diseases as muscular lesions, peripheral neuropathy, chronic solvent encephalopathy, gastrointestinal cancer caused by wood dust, benzene-induced leukemia, the infectious occupational diseases such as anthrax or hepatitis, lead poisoning, mercury poisoning, cadmium poisoning, and occupational dermatitis.

2. Senator Hatch's comments here do not reflect a clear reading of S.79.

It is important to recognize that S.79 does not indicate that a single study, either epidemiologic or toxicologic, will ever in and of itself trigger notification of exposed workers. Instead, a single significantly positive study triggers a review process. In some instances, of which I am personally aware, a well conducted single study has indeed identified a chemical compound as hazardous and thus has triggered worker notification. An outstanding example is the notification of all vinyl chloride polymerization workers in the United States that they were at risk of angiosarcoma of the liver after publication of a single short report indicating that three cases of this exceptionally rare malignancy had occurred among vinyl chloride polymerization workers in a plant in Louisville, Kentucky.

Much more typically, however, a single study does not trigger notification. Instead, it is the strong consensus of the scientific community that a primary criterion for establishing the existence of a causal relationship between a toxic agent and a disease is the repeated demonstration of that relationship in numerous studies, both human and animal. Such has been the case for many known occupational toxins, such as arsenic, benzene, coal tar pitch, radiation, and beta-naphthylamine. The process by which the scientific community reviews and evaluates data and concludes ultimately that a cause and effect relationship exists between exposure and disease is elegantly illustrated by the deliberative process of the International Agency for Research on Cancer (IARC), the cancer agency of the World Health Organization. IARC has established a very comprehensive series of rules by which the results of published studies, both epiedemiologic and toxicologic are scrupulously evaluated by a panel of experts. The details of this process are described in the IARC Preamble, a copy of which is attached.

The procedures employed by IARC will almost certainly serve as a model for deliberations to be undertaken by the expert panel convened by S.79. The approaches employed by such a panel are scientifically sound. They rest ultimately on the demonstration of statistically significant associations between toxic exposure and human disease. Occasionally, a single well conducted study may indeed cause the expert review board to reach the scientifically sound judgment that hazard exists and that the notification process should be triggered. Usually, however, a constellation of convergent studies will be required to convince the review panel to trigger the notification process.

3. The number of workers in the United States who are occupationally exposed to carcinogens, reproductive toxins, neurologic toxins and mutagens is numbered in the millions, according to data from the National Occupational Exposure Survey conducted by the National Institute for Occupational Safety and Health (NIOSH). In this context, a requirement for notification of at least 100,000 workers a year does not seem an enormous task, nor does it seem likely to strain the bounds of scientific credibility. It is important to emphasize, however, that the Public Health Service be given sufficient resources to undertake this task.

4. The National Institute for Occupational Safety and Health, many university groups, and scientific groups in industry have all had extensive experience in tracing populations of workers in the context of performing epidemiologic studies. Typically in these endeavors, the goal is to trace at least 95 percent of an exposed workforce.

   Our experience indicates that the average cost of tracing each worker in such populations is 30 to 40 dollars.

5. The numbers of workers to be screened and the frequency of visits to a doctor or nurse will depend on the nature of the condition under surveillance. Workers exposed to asbestos are, for example, examined and given a chest X-ray approximately every three years. Workers exposed to bladder carcinogens receive first level screening consisting of examination of the urine for blood every one to two years; cystoscopy and more intensive follow-up examination is triggered by the finding of blood in the urine. Patternmakers in the automobile industry who are at increased risk of colon cancer are given colonoscopic examinations every one to two years. Workers at elevated risk for skin cancer as the result of excessive occupational exposure to sunlight or to coal tar pitch should be examined approximately every year to detect new lesions.

   All of these procedures will, if properly performed, detect illness early and lead to the saving of lives as well as to the prevention of needless pain, suffering and disability.

   Additionally, it should be recognized that prevention is good business. Early intervention not only prevents suffering but also saves medical costs. As a result, insurance premiums may be reduced and the cost burden on the federal government will be reduced. The data produced by Ruttenberg and Powers in their review of the Bladder Notification Project undertaken by NIOSH in Augusta, Georgia tabulates a number of the cost savings which can result from notification and pre-emptive medical surveillance of an exposed population.

In summary, it is a misrepresentation of reality to portray worker notification as a procedure which poses an inevitable financial drain on business and the federal government. In fact, notification of high risk workers if undertaken in an open and cooperative spirit by forward thinking business leaders, trade union officials, politicians, government officials, and physicians will save money, save lives, save pain and suffering, and be a credit to the capacity of our society for enlightened action.

I hope that these answers are responsive to Senator Hatch's questions. If you desire any further clarification, please do not hesitate to call upon me.

Sincerely,

Philip J. Landrigan, M.D.
Professor

PJL:ss

24

WORLD HEALTH ORGANIZATION

INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

IARC MONOGRAPHS

ON THE

EVALUATION OF THE CARCINOGENIC RISK OF CHEMICALS TO HUMANS

Some Chemicals Used in Plastics and Elastomers

VOLUME 39

This publication represents the views and expert opinions
of an IARC Working Group on the
Evaluation of the Carcinogenic Risk of Chemicals to Humans
which met in Lyon,

11-18 June, 1985

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IARC MONOGRAPHS PROGRAMME ON THE EVALUATION OF THE CARCINOGENIC RISK OF CHEMICALS TO HUMANS[1]

PREAMBLE

1. BACKGROUND

In 1969, the International Agency for Research on Cancer (IARC) initiated a programme to evaluate the carcinogenic risk of chemicals to humans and to produce monographs on individual chemicals. Following the recommendations of an ad-hoc Working Group, which met in Lyon in 1979 to prepare criteria to select chemicals for *IARC Monographs*(1), the *Monographs* programme was expanded to include consideration of exposures to complex mixtures which may occur, for example, in many occupations or as a result of human habits.

The criteria established in 1971 to evaluate carcinogenic risk to humans were adopted by all the working groups whose deliberations resulted in the first 16 volumes of the *IARC Monographs* series. This preamble reflects subsequent re-evaluation of those criteria by working groups which met in 1977(2), 1978(3), 1982(4) and 1983(5).

2. OBJECTIVE AND SCOPE

The objective of the programme is to elaborate and publish in the form of monographs critical reviews of data on carcinogenicity for chemicals, groups of chemicals, industrial processes and other complex mixtures to which humans are known to be exposed, to evaluate the data in terms of human risk with the help of international working groups of experts, and to indicate where additional research efforts are needed. These evaluations are intended to assist national and international authorities in formulating decisions concerning preventive measures. No recommendation is given concerning legislation, since this depends on risk-benefit evaluations, which seem best made by individual governments and/or other international agencies.

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[1] This project is supported by PHS Grant No. 1 U01 CA33193-03 awarded by the US National Cancer Institute, Department of Health and Human Services.

The *IARC Monographs* are recognized as an authoritative source of information on the carcinogenicity of environmental and other chemicals. A users' survey, made in 1984, indicated that the monographs are consulted by various agencies in 45 countries. As of April 1986, 39 volumes of the *Monographs* had been published or were in press. Five supplements have been published: two summaries of evaluations of chemicals associated with human cancer, an evaluation of screening assays for carcinogens, and two cross indexes of synonyms and trade names of chemicals evaluated in the series(6).

3. SELECTION OF CHEMICALS AND COMPLEX EXPOSURES FOR MONOGRAPHS

The chemicals (natural and synthetic including those which occur as mixtures and in manufacturing processes) and complex exposures are selected for evaluation on the basis of two main criteria: (a) there is evidence of human exposure, and (b) there is some experimental evidence of carcinogenicity and/or there is some evidence or suspicion of a risk to humans. In certain instances, chemical analogues are also considered. The scientific literature is surveyed for published data relevant to the *Monographs* programme; and the IARC *Survey of Chemicals Being Tested for Carcinogenicity*(7) often indicates those chemicals that may be scheduled for future meetings.

As new data on chemicals for which monographs have already been prepared become available, re-evaluations are made at subsequent meetings, and revised monographs are published.

4. WORKING PROCEDURES

Approximately one year in advance of a meeting of a working group, a list of the substances or complex exposures to be considered is prepared by IARC staff in consultation with other experts. Subsequently, all relevant biological data are collected by IARC; recognized sources of information on chemical carcinogenesis and on-line systems such as CANCERLINE, MEDLINE and TOXLINE are used in conjunction with US Public Health Service Publication No. 149(8). Bibliographical sources for data on mutagenicity and teratogenicity are the Environmental Mutagen Information Center and the Environmental Teratology Information Center, both located at the Oak Ridge National Laboratory, TN, USA.

The major collection of data and the preparation of first drafts for the sections on chemical and physical properties, on production and use, on occurrence, and on analysis are carried out by Tracor Jitco, Inc., and its subcontractor, Technical Resources, Inc., both in Rockville, MD, USA, under a separate contract with the US National Cancer Institute. Most of the data so obtained refer to the USA and Japan; IARC attempts to supplement this information with that from other sources in Europe. Representatives from industrial associations may assist in the preparation of sections describing industrial processes.

Six months before the meeting, articles containing relevant biological data are sent to an expert(s), or are used by IARC staff, to prepare first drafts of the sections on biological effects. The complete drafts are then compiled by IARC staff and sent, prior to the meeting, to all participants of the Working Group for their comments.

The Working Group meets in Lyon for seven to eight days to discuss and finalize the texts of the monographs and to formulate the evaluations. After the meeting, the master copy of each monograph is verified by consulting the original literature, edited by a professional editor and prepared for reproduction. The aim is to publish monographs within nine months of the Working Group meeting. Each volume of monographs is printed in 4000 copies for distribution to governments, regulatory agencies and interested scientists. The monographs are also available *via* the WHO Distribution and Sales Service.

These procedures are followed for the preparation of most volumes of monographs, which cover chemicals and groups of chemicals; however, they may vary when the subject matter is an industry or life-style factor.

5. DATA FOR EVALUATIONS

With regard to biological data, only reports that have been published or accepted for publication are reviewed by the working groups, although a few exceptions have been made: in certain instances, reports from government agencies that have undergone peer review and are widely available are considered. The monographs do not cite all of the literature on a particular chemical or complex exposure: only those data considered by the Working Group to be relevant to the evaluation of carcinogenic risk to humans are included.

Anyone who is aware of data that have been published or are in press which are relevant to the evaluations of the carcinogenic risk to humans of chemicals or complex exposures for which monographs have appeared is asked to make them available to the Unit of Carcinogen Identification and Evaluation, Division of Environmental Carcinogenesis, International Agency for Research on Cancer, Lyon, France.

6. THE WORKING GROUP

The tasks of the Working Group are five-fold: (a) to ascertain that all data have been collected; (b) to select the data relevant for evaluation; (c) to ensure that the summaries of the data enable the reader to follow the reasoning of the Working Group; (d) to judge the significance of the results of experimental and epidemiological studies; and (e) to make an evaluation of the carcinogenicity of the chemical or complex exposure.

Working Group participants who contributed to the consideration and evaluation of chemicals or complex exposures within a particular volume are listed, with their addresses, at the beginning of each publication. Each member serves as an individual scientist and not as a representative of any organization or government. In addition, observers are often invited from national and international agencies and industrial associations.

7. GENERAL PRINCIPLES APPLIED BY THE WORKING GROUP IN EVALUATING CARCINOGENIC RISK OF CHEMICALS OR COMPLEX MIXTURES

The widely accepted meaning of the term 'chemical carcinogenesis', and that used in these monographs, is the induction by chemicals (or complex mixtures of chemicals) of neoplasms that are not usually observed, the earlier induction of neoplasms that are commonly observed, and/or the induction of more neoplasms than are usually found — although fundamentally different mechanisms may be involved in these three situations. Etymologically, the term 'carcinogenesis' means the induction of cancer, that is, of malignant neoplasms; however, the commonly accepted meaning is the induction of various types of neoplasms or of a combination of malignant and benign tumours. In the monographs, the words 'tumour' and 'neoplasm' are used interchangeably. (In the scientific literature, the terms 'tumorigen', 'oncogen' and 'blastomogen' have all been used synonymously with 'carcinogen', although occasionally 'tumorigen' has been used specifically to denote a substance that induces benign tumours.)

(a) Experimental Evidence

(i) *Evidence for carcinogenicity in experimental animals*

The Working Group considers various aspects of the experimental evidence reported in the literature and formulates an evaluation of that evidence.

Qualitative aspects: Both the interpretation and evaluation of a particular study as well as the overall assessment of the carcinogenic activity of a chemical (or complex mixture) involve several considerations of qualitative importance, including: (a) the experimental parameters under which the chemical was tested, including route of administration and exposure, species, strain, sex, age, etc.; (b) the consistency with which the chemical has been shown to be carcinogenic, e.g., in how many species and at which target organ(s); (c) the spectrum of neoplastic response, from benign neoplasm to multiple malignant tumours; (d) the stage of tumour formation in which a chemical may be involved: some chemicals act as complete carcinogens and have initiating and promoting activity, while others may have promoting activity only; and (e) the possible role of modifying factors.

There are problems not only of differential survival but of differential toxicity, which may be manifested by unequal growth and weight gain in treated and control animals. These complexities are also considered in the interpretation of data.

Many chemicals induce both benign and malignant tumours. Among chemicals that have been studied extensively, there are few instances in which the only neoplasms induced are benign. Benign tumours may represent a stage in the evolution of a malignant neoplasm or they may be 'end-points' that do not readily undergo transition to malignancy. If a substance is found to induce only benign tumours in experimental animals, it should nevertheless be suspected of being a carcinogen, and it requires further investigation.

Hormonal carcinogenesis: Hormonal carcinogenesis presents certain distinctive features: the chemicals involved occur both endogenously and exogenously; in many instances, long exposure is required; and tumours occur in the target tissue in association with a stimulation of non-neoplastic growth, although in some cases hormones promote the proliferation of tumour cells in a target organ. For hormones that occur in excessive amounts, for hormone-mimetic agents and for agents that cause hyperactivity or imbalance in the endocrine system, evaluative methods comparable with those used to identify chemical carcinogens may be required; particular emphasis must be laid on quantitative aspects and duration of exposure. Some chemical carcinogens have significant side effects on the endocrine system, which may also result in hormonal carcinogenesis. Synthetic hormones and anti-hormones can be expected to possess other pharmacological and toxicological actions in addition to those on the endocrine system, and in this respect they must be treated like any other chemical with regard to intrinsic carcinogenic potential.

Complex mixtures: There is an increasing amount of data from long-term carcinogenicity studies on complex mixtures and on crude materials obtained by sampling in occupational environments. The representativity of such samples must be considered carefully.

Quantitative aspects: Dose-response studies are important in the evaluation of carcinogenesis: the confidence with which a carcinogenic effect can be established is strengthened by the observation of an increasing incidence of neoplasms with increasing exposure.

The assessment of carcinogenicity in animals is frequently complicated by recognized differences among the test animals (species, strain, sex, age) and route and schedule of administration; often, the target organs at which a cancer occurs and its histological type may vary with these parameters. Nevertheless, indices of carcinogenic potency in particular experimental systems (for instance, the dose-rate required under continuous exposure to halve the probability of the animals remaining tumourless(9)) have been formulated in the hope that, at least among categories of fairly similar agents, such indices may be of some predictive value in other species, including humans.

Chemical carcinogens share many common biological properties, which include metabolism to reactive (electrophilic(10-11)) intermediates capable of interacting with DNA. However, they may differ widely in the dose required to produce a given level of tumour induction. The reason for this variation in dose-response is not understood, but it may be due to differences in metabolic activation and detoxification processes, in different DNA repair capacities among various organs and species or to the operation of qualitatively distinct mechanisms.

Statistical analysis of animal studies: It is possible that an animal may die prematurely from unrelated causes, so that tumours that would have arisen had the animal lived longer may not be observed; this possibility must be allowed for. Various analytical techniques have been developed which use the assumption of independence of competing risks to allow for the effects of intercurrent mortality on the final numbers of tumour-bearing animals in particular treatment groups.

For externally visible tumours and for neoplasms that cause death, methods such as Kaplan-Meier (i.e., 'life-table', 'product-limit' or 'actuarial') estimates(9), with associated significance tests(12), have been recommended. For internal neoplasms that are discovered 'incidentally'(12) at autopsy but that did not cause the death of the host, different estimates(13) and significance tests(12) may be necessary for the unbiased study of the numbers of tumour-bearing animals.

The design and statistical analysis of long-term carcinogenicity experiments were reviewed in Supplement 2 to the *Monographs* series(14). That review outlined the way in which the context of observation of a given tumour (fatal or incidental) could be included in an analysis yielding a single combined result. This method requires information on time to death for each animal and is therefore comparable to only a limited extent with analyses which include global proportions of tumour-bearing animals.

Evaluation of carcinogenicity studies in experimental animals: The evidence of carcinogenicity in experimental animals is assessed by the Working Group and judged to fall into one of four groups, defined as follows:

(1) *Sufficient evidence* of carcinogenicity is provided when there is an increased incidence of malignant tumours: (a) in multiple species or strains; or (b) in multiple experiments (preferably with different routes of administration or using different dose levels); or (c) to an unusual degree with regard to incidence, site or type of tumour, or age at onset. Additional evidence may be provided by data on dose-response effects.

(2) *Limited evidence* of carcinogenicity is available when the data suggest a carcinogenic effect but are limited because: (a) the studies involve a single species, strain or experiment; or (b) the experiments are restricted by inadequate dosage levels, inadequate duration of exposure to the agent, inadequate period of follow-up, poor survival, too few animals, or inadequate reporting; or (c) the neoplasms produced often occur spontaneously and, in the past, have been difficult to classify as malignant by histological criteria alone (e.g., lung adenomas and adenocarcinomas and liver tumours in certain strains of mice).

(3) *Inadequate evidence* of carcinogenicity is available when, because of major qualitative or quantitative limitations, the studies cannot be interpreted as showing either the presence or absence of a carcinogenic effect.

(4) *No evidence* of carcinogenicity applies when several adequate studies are available which show that, within the limits of the tests used, the chemical or complex mixture is not carcinogenic.

It should be noted that the categories *sufficient evidence* and *limited evidence* refer only to the strength of the experimental evidence that these chemicals or complex mixtures are carcinogenic and not to the extent of their carcinogenic activity nor to the mechanism involved. The classification of any chemical may change as new information becomes available.

(ii) *Evidence for activity in short-term tests*[1]

Many short-term tests bearing on postulated mechanisms of carcinogenesis or on the properties of known carcinogens have been developed in recent years. The induction of cancer is thought to proceed by a series of steps, some of which have been distinguished experimentally (15-19). The first step — initiation — is thought to involve damage to DNA, resulting in heritable alterations in or rearrangements of genetic information. Most short-term tests in common use today are designed to evaluate the genetic activity of a substance.

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[1] Based on the recommendations of a working group which met in 1983(5)

Data from these assays are useful for identifying potential carcinogenic hazards, in identifying active metabolites of known carcinogens in human or animal body fluids, and in helping to elucidate mechanisms of carcinogenesis. Short-term tests to detect agents with tumour-promoting activity are, at this time, insufficiently developed.

Because of the large number of short-term tests, it is difficult to establish rigid criteria for adequacy that would be applicable to all studies. General considerations relevant to all tests, however, include (a) that the test system be valid with respect to known animal carcinogens and noncarcinogens; (b) that the experimental parameters under which the chemical (or complex mixture) is tested include a sufficiently wide dose range and duration of exposure to the agent and an appropriate metabolic system; (c) that appropriate controls be used; and (d) that the purity of the compound or, in the case of complex mixtures, that the source and representativity of the sample being tested be specified. Confidence in positive results is increased if a dose-response relationship is demonstrated and if this effect has been reported in two or more independent studies.

Most established short-term tests employ as end-points well-defined genetic markers in prokaryotes and lower eukaryotes and in mammalian cell lines. The tests can be grouped according to the end-point detected:

Tests of *DNA damage*. These include tests for covalent binding to DNA, induction of DNA breakage or repair, induction of prophage in bacteria and differential survival of DNA repair-proficient/-deficient strains of bacteria.

Tests of *mutation* (measurement of heritable alterations in phenotype and/or genotype). These include tests for detection of the loss or alteration of a gene product, and change of function through forward or reverse mutation, recombination and gene conversion; they may involve the nuclear genome, the mitochondrial genome and resident viral or plasmid genomes.

Tests of *chromosomal effects*. These include tests for detection of changes in chromosome number (aneuploidy), structural chromosomal aberrations, sister chromatid exchanges, micronuclei and dominant-lethal events. This classification does not imply that some chromosomal effects are not mutational events.

Tests for *cell transformation*, which monitor the production of preneoplastic or neoplastic cells in culture, are also of importance because they attempt to simulate essential steps in cellular carcinogenesis. These assays are not grouped with those listed above since the mechanisms by which chemicals induce cell transformation may not necessarily be the result of genetic change.

The selection of specific tests and end-points for consideration remains flexible and should reflect the most advanced state of knowledge in this field.

The data from short-term tests are summarized by the Working Group and the test results tabulated according to the end-points detected and the biological complexities of the test systems. The format of the table used is shown below. In these tables, a '+' indicates that the compound was judged by the Working Group to be significantly positive in one or more assays for the specific end-point and level of biological complexity; '-' indicates that it was judged to be negative in one or more assays; and '?' indicates that there were contradictory results from different laboratories or in different biological systems, or that the result was judged to be equivocal. These judgements reflect the assessment by the Working Group of the quality of the data (including such factors as the purity of the test compound, problems of metabolic activation and appropriateness of the test system) and the relative significance of the component tests.

Overall assessment of data from short-term tests

	Genetic activity			Cell transformation
	DNA damage	Mutation	Chromosomal effects	
Prokaryotes				
Fungi/ Green plants				
Insects				
Mammalian cells (*in vitro*)				
Mammals (*in vivo*)				
Humans (*in vivo*)				

An overall assessment of the evidence for *genetic activity* is then made on the basis of the entries in the table, and the evidence is judged to fall into one of four categories, defined as follows:

(1) *Sufficient evidence* is provided by at least three positive entries, one of which must involve mammalian cells *in vitro* or *in vivo* and which must include at least two of three end-points — DNA damage, mutation and chromosomal effects.

(2) *Limited evidence* is provided by at least two positive entries.

(3) *Inadequate evidence* is available when there is only one positive entry or when there are too few data to permit an evaluation of an absence of genetic activity or when there are unexplained, inconsistent findings in different test systems.

(4) *No evidence* applies when there are only negative entries; these must include entries for at least two end-points and two levels of biological complexity, one of which must involve mammalian cells *in vitro* or *in vivo*.

It is emphasized that the above definitions are operational, and that the assignment of a chemical or complex mixture into one of these categories is thus arbitrary.

In general, emphasis is placed on positive results; however, in view of the limitations of current knowledge about mechanisms of carcinogenesis, certain cautions should be respected: (i) At present, short-term tests should not be used by themselves to conclude whether or not an agent is carcinogenic nor can they predict reliably the relative potencies of compounds as carcinogens in intact animals. (ii) Since the currently available tests do not detect all classes of agents that are active in the carcinogenic process (e.g., hormones), one must be cautious in utilizing these tests as the sole criterion for setting priorities in carcinogenesis research and in selecting compounds for animal bioassays. (iii) Negative results from short-term tests cannot be considered as evidence to rule out carcinogenicity, nor does lack of demonstrable genetic activity attribute an epigenetic or any other property to a substance (5).

(b) Evaluation of Carcinogenicity in Humans

Evidence of carcinogenicity can be derived from case reports, descriptive epidemiological studies and analytical epidemiological studies.

An analytical study that shows a positive association between an exposure and a cancer may be interpreted as implying causality to a greater or lesser extent, on the basis of the following criteria: (a) There is no identifiable positive bias. (By 'positive bias' is meant the operation of factors in study design or execution that lead erroneously to a more strongly positive association between an exposure and disease than in fact exists. Examples of positive bias include, in case-control studies, better documentation of the exposure for cases than for controls, and, in cohort studies, the use of better means of detecting cancer in exposed individuals than in individuals not exposed.) (b) The possibility of positive confounding has been considered. (By 'positive confounding' is meant a situation in which the relationship between an exposure and a disease is rendered more strongly positive than it truly is as a result of an association between that exposure and another exposure which either causes or prevents the disease. An example of positive confounding is the association between coffee consumption and lung cancer, which results from their joint association with cigarette smoking.) (c) The association is unlikely to be due to chance alone. (d) The association is strong. (e) There is a dose-response relationship.

In some instances, a single epidemiological study may be strongly indicative of a cause-effect relationship; however, the most convincing evidence of causality comes when several independent studies done under different circumstances result in 'positive' findings.

Analytical epidemiological studies that show no association between an exposure and a cancer ('negative' studies) should be interpreted according to criteria analogous to those listed above: (a) there is no identifiable negative bias, (b) the possibility of negative confounding has been considered; and (c) the possible effects of misclassification of exposure or outcome have been weighed. In addition, it must be recognized that the probability that a given study can detect a certain effect is limited by its size. This can be perceived from the confidence limits around the estimate of association or relative risk. In a study regarded as 'negative', the upper confidence limit may indicate a relative risk substantially greater than unity; in that case, the study excludes only relative risks that are above the upper limit. This usually means that a 'negative' study must be large to be convincing. Confidence in a 'negative' result is increased when several independent studies carried out under different circumstances are in agreement. Finally, a 'negative' study may be considered to be relevant only to dose levels within or below the range of those observed in the study and is pertinent only if sufficient time has elapsed since first human exposure to the agent. Experience with human cancers of known etiology suggests that the period from first exposure to a chemical carcinogen to development of clinically observed cancer is usually measured in decades and may be in excess of 30 years.

The evidence for carcinogenicity from studies in humans is assessed by the Working Group and judged to fall into one of four groups, defined as follows:

(1) *Sufficient evidence* of carcinogenicity indicates that there is a causal relationship between the exposure and human cancer.

(2) *Limited evidence* of carcinogenicity indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias or confounding, could not adequately be excluded.

(3) *Inadequate evidence* of carcinogenicity, which applies to both positive and negative evidence, indicates that one of two conditions prevailed: (a) there are few pertinent data; or (b) the available studies, while showing evidence of association, do not exclude chance, bias or confounding.

(4) *No evidence* of carcinogenicity applies when several adequate studies are available which do not show evidence of carcinogenicity.

(c) Relevance of Experimental Data to the Evaluation of Carcinogenic Risk to Humans

Information compiled from the first 38 volumes of the *IARC Monographs* shows that, of the chemicals or groups of chemicals now generally accepted to cause or probably to cause cancer in humans, all of those that have been tested appropriately produce cancer in at least one animal species. For several of the chemicals (e.g., aflatoxins, 4-aminobiphenyl, diethylstilboestrol, melphalan, mustard gas and vinyl chloride), evidence of carcinogenicity in experimental animals preceded evidence obtained from epidemiological studies or case reports.

For many of the chemicals (or complex mixtures) evaluated in the *IARC Monographs* for which there is *sufficient evidence* of carcinogenicity in animals, data relating to carcinogenicity for humans are either insufficient or nonexistent. **In the absence of adequate data on humans, it is reasonable, for practical purposes, to regard chemicals or exposures for which there is sufficient evidence of carcinogenicity in animals as if they presented a carcinogenic risk to humans.** The use of the expressions 'for practical purposes' and 'as if they presented a carcinogenic risk' indicates that, at the present time, a correlation between carcinogenicity in animals and possible human risk cannot be made on a purely scientific basis, but only pragmatically. Such a pragmatic correlation may be useful to regulatory agencies in making decisions related to the primary prevention of cancer.

In the present state of knowledge, it would be difficult to define a predictable relationship between the dose (mg kg bw per day) of a particular chemical required to produce cancer in test animals and the dose that would produce a similar incidence of cancer in humans. Some data, however, suggest that such a relationship may exist(20,21), at least for certain classes of carcinogenic chemicals, although no acceptable method is currently available for quantifying the possible errors that may be involved in such an extrapolation procedure.

8. EXPLANATORY NOTES ON THE CONTENTS OF MONOGRAPHS ON CHEMICALS AND COMPLEX MIXTURES

These notes apply to the format of most monographs, except for those that address industries or life-style factors. Thus, sections 1 and 2, as described below, are applicable in monographs on chemicals or groups of chemicals; in other monographs, they may be replaced by sections on the history of an industry or habit, a description of a process and other relevant information.

(a) Chemical and Physical Data (Section 1)

The Chemical Abstracts Services Registry Number, the latest Chemical Abstracts Primary Name (Ninth Collective Index)(22) and the IUPAC Systematic Name(23) are recorded in section 1. Other synonyms and trade names are given, but the list is not necessarily comprehensive. Some of the trade names may be those of mixtures in which the compound being evaluated is only one of the ingredients.

The structural and molecular formulae, molecular weight and chemical and physical properties are given. The properties listed refer to the pure substance, unless otherwise specified, and include, in particular, data that might be relevant to identification, environmental fate and human exposure, and biological effects, including carcinogenicity.

A separate description of the composition of technical products includes available information on impurities and formulated products.

(b) Production, Use, Occurrence and Analysis (Section 2)

The purpose of section 2 is to provide indications of the extent of past and present human exposure to the chemical.

Monographs on occupational exposures to complex mixtures or exposures to complex mixtures resulting from human habits include sections on: historical perspectives; description of the industry or habit; manufacturing processes and use patterns; exposures in the workplace; chemistry of the complex mixture.

(i) *Synthesis*

Since cancer is a delayed toxic effect, the dates of first synthesis and of first commercial production of the chemical are provided. This information allows a reasonable estimate to be made of the date before which no human exposure could have occurred. In addition, methods of synthesis used in past and present commercial production are described.

(ii) *Production*

Since Europe, Japan and the USA are reasonably representative industrialized areas of the world, most data on production, foreign trade and uses are obtained from those regions. It should not, however, be inferred that those areas or nations are the sole or even necessarily the major sources or users of any individual chemical.

Production and foreign trade data are obtained from both governmental and trade publications. In some cases, separate production data on organic chemicals manufactured in the USA are not available because their publication could disclose confidential information. In such cases, an indication of the minimum quantity produced can be inferred from the number of companies reporting commercial production. Each company is required to report on individual chemicals if the annual sales value or production volume exceeds a specified minimum level. These levels vary for chemicals classified for different uses, e.g., medicinals and plastics; in fact, the minimal reportable level for annual sales value ranges from $1000-$50 000, and the minimal reportable level for annual production volume ranges from 450-22 700 kg for different classes of use. Data on production are also obtained by means of general questionnaires sent to companies thought to produce the compounds being evaluated. Information from the completed questionnaires is compiled, by country, and the resulting estimates of production are included in the individual monographs.

(iii) *Use*

Information on uses is usually obtained from published sources but is often complemented by direct contact with manufacturers. Some uses identified may not be current or major applications, and the coverage is not necessarily comprehensive. In the case of drugs, mention of their therapeutic uses does not necessarily represent current practice nor does it imply judgement as to their clinical efficacy.

Statements concerning regulations and standards (e.g., pesticide registrations, maximum levels permitted in foods, occupational standards and allowable limits) in specific countries may not reflect the most recent situation, since such standards are continuously reviewed and modified. The absence of information on regulatory status for a country should not be taken to imply that that country does not have regulations with regard to the chemical.

(iv) *Occurrence*

Information on the occurrence of a chemical in the environment is obtained from published data, including that derived from the monitoring and surveillance of levels of the chemical in occupational environments, air, water, soil, foods and tissues of animals and humans. When no published data are available to the Working Group, unpublished reports, deemed appropriate, may be considered. When available, data on the generation, persistence and bioaccumulation of a chemical are also included.

(v) *Analysis*

The purpose of the section on analysis is to give the reader an overview, rather than a complete list, of current methods cited in the literature. No critical evaluation or recommendation of any of the methods is meant or implied.

(c) Biological Data Relevant to the Evaluation of Carcinogenic Risk to Humans (Section 3)

In general, the data recorded in section 3 are summarized as given by the author; however, comments made by the Working Group on certain shortcomings of reporting, of statistical analysis or of experimental design are given in square brackets. The nature and extent of impurities/contaminants in the chemicals being tested are given when available.

(i) *Carcinogenicity studies in animals*

The monographs are not intended to cover all reported studies. A few studies are purposely omitted because they are inadequate (e.g., too short a duration, too few animals, poor survival) or because they are judged irrelevant for the purpose of the evaluation. In certain cases, however, such studies are mentioned briefly, particularly when the information is considered to be a useful supplement to other reports or when it is the only data available. Their inclusion does not, however, imply acceptance of the adequacy of their experimental design or of the analysis and interpretation of their results.

Mention is made of all routes of administration by which the test material has been adequately tested and of all species in which relevant tests have been done(24). In most cases, animal strains are given. Quantitative data are given to indicate the order of magnitude of the effective carcinogenic doses. In general, the doses and schedules are indicated as they appear in the original report; sometimes units have been converted for easier comparison. Experiments in which the compound was administered in conjunction with known carcinogens and experiments on factors that modify the carcinogenic effect are also reported. Experiments on the carcinogenicity of known metabolites and derivatives are also included.

(ii) *Other relevant biological data*

LD_{50} data are given when available, and other data on toxicity are included when considered relevant.

Data on effects on reproduction, on teratogenicity and embryo- and fetotoxicity and on placental transfer, from studies in experimental animals and from observations in humans, are included when considered relevant.

Information is given on absorption, distribution and excretion. Data on metabolism are usually restricted to studies that show the metabolic fate of the chemical in experimental animals and humans, and comparisons of data from animals and humans are made when possible.

Data from short-term tests are also included. In addition to the tests for genetic activity and cell transformation described previously (see pages 18-19), data from studies of related effects, but for which the relevance to the carcinogenic process is less well established, may also be mentioned.

The criteria used for considering short-term tests and for evaluating their results have been described (see pages 19-21). In general, the authors' results are given as reported. An assessment of the data by the Working Group which differs from that of the authors, and comments concerning aspects of the study that might affect its interpretation are given in square brackets. Reports of studies in which few or no experimental details are given, or in which the data on which a reported positive or negative result is based are not available for examination, are cited, but are identified as 'abstract' or 'details not given' and are not considered in the summary tables or in making the overall assessment of genetic activity.

For several recent reviews on short-term tests, see IARC(24), Montesano *et al.*(25), de Serres and Ashby(26), Sugimura *et al.*(27), Bartsch *et al.*(28) and Hollstein *et al.*(29).

(iii) *Case reports and epidemiological studies of carcinogenicity to humans*

Observations in humans are summarized in this section. These include case reports, descriptive epidemiological studies (which correlate cancer incidence in space or time to an exposure) and analytical epidemiological studies of the case-control or cohort type. In principle, a comprehensive coverage is made of observations in humans; however, reports are excluded when judged to be clearly not pertinent. This applies in particular to case reports, in which either the clinico-pathological description of the tumours or the exposure history, or both, are poorly described; and to published routine statistics, for example, of cancer mortality by occupational category, when the categories are so broadly defined as to contribute virtually no specific information on the possible relation between cancer occurrence and a given exposure. Results of studies are assessed on the basis of the data and analyses that are presented in the published papers. Some additional analyses of the published data may be performed by the Working Group to gain better insight into the relation between cancer occurrence and the exposure under consideration. The Working Group may use these analyses in its assessment of the evidence or may actually include them in the text to summarize a study; in such cases, the results of the supplementary analyses are given in square brackets. Any comments by the Working Group are also reported in square brackets; however, these are kept to a minimum, being restricted to those instances in which it is felt that an important aspect of a study, directly impinging on its interpretation, should be brought to the attention of the reader.

(d) Summary of Data Reported and Evaluation (Section 4)

Section 4 summarizes the relevant data from animals and humans and gives the critical views of the Working Group on those data.

(i) *Exposures*

Human exposure to the chemical or complex mixture is summarized on the basis of data on production, use and occurrence.

(ii) *Experimental data*

Data relevant to the evaluation of the carcinogenicity of the test material in animals are summarized in this section. The animal species mentioned are those in which the carcinogenicity of the substance was clearly demonstrated. Tumour sites are also indicated. If the substance has produced tumours after prenatal exposure or in single-dose experiments, this is indicated. Dose-response data are given when available.

Significant findings on effects on reproduction and prenatal toxicity, and results from short-term tests for genetic activity and cell transformation assays are summarized, and the latter are presented in tables. An overall assessment is made of the degree of evidence for genetic activity in short-term tests.

(iii) *Human data*

Case reports and epidemiological studies that are considered to be pertinent to an assessment of human carcinogenicity are described. Other biological data that are considered to be relevant are also mentioned.

(iv) *Evaluation*

This section comprises evaluations by the Working Group of the degrees of evidence for carcinogenicity of the exposure to experimental animals and to humans. An overall evaluation is then made of the carcinogenic risk of the chemical or complex mixture to humans. This section should be read in conjunction with pages 18 and 22 of this Preamble for definitions of degrees of evidence.

When no data are available from epidemiological studies but there is *sufficient evidence* that the exposure is carcinogenic to animals, a footnote is included, reading: 'In the absence of adequate data on humans, it is reasonable, for practical purposes, to regard chemicals or exposures for which there is *sufficient evidence* of carcinogenicity in animals as if they presented a carcinogenic risk to humans' (pp. 22-23).

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Senator **Metzenbaum**. Dr. Seffrin, representing the American Cancer Society.

Dr. **Seffrin**. Thank you, Mr. Chairman.

I am John R. Seffrin, Professor and Chairman of the Department of Applied Health Science at Indiana University and Director of its Center for Health and Safety Studies.

However, I am here today representing the American Cancer Society, as I have been a long-time volunteer for that organization and currently serve as the Vice President of the Society's National Board of Directors.

I would like to comment briefly on S. 79, the High Risk Occupational Disease Notification and Prevention Act of 1987.

In March of 1986, the American Cancer Society's National Board of Directors approved the following resolution regarding similar legislation which was, as you know, before your last Congress. And I will quote very briefly: "Resolved: The American Cancer Society supports the intent of S. 2050 and H.R. 1309 and will work with members of Congress to secure legislation to prevent and modify risks of occupationally induced cancer."

That action was consistent with a policy statement adopted by the Society's Board of Directors in 1980 which in part reads, and I quote again: "Resolved: The American Cancer Society believes that where there is information that chemicals or other industrial agents used in the workplace are known to cause cancer, or are scientifically suspect of causing cancer in humans, the employee has a right to such information."

We believe that Senator Metzenbaum has presented a realistic and practical bill which, if enacted, would address a very important need, namely, the establishment of a non-threatening system for monitoring workers in business and industrial situations who are, by the very nature of their work, exposed to substances known or suspected of being toxic.

By being monitored in this systematic and standardized way, those who may be receiving unacceptably high exposure to those toxic substances can be identified, hopefully, before it is too late to reverse the situation, and measures can be taken by the worker and/or management to reduce such exposure.

Mr. Chairman, primary prevention of cancer, of course, is the most desirable means of reducing cancer morbidity as well as cancer mortality in the United States. Not only does the primary prevention of cancer preserve the quality of life of the worker, but very importantly as regarding this bill, it obviates the need for expensive treatment of a life-threatening disease.

The American Cancer Society's purpose is to do everything possible to eliminate cancer as a serious threat to human health. Our principal efforts are through education, research and service to the cancer patient. We support the intent of the proposed legislation because it directly addresses our objective as stated in the 1980 position, and it addresses a very important issue of acknowledging, understanding and acting on some of the vast range of knowledge we have gained in recent years that we now know regarding the etiology of human cancer.

We would not expect that enactment of this or any other legislation would result in the total elimination of workers' cancer risk.

We know that cigarette smoking dramatically enhances the carcinogenic effects of many toxic agents, and it is still unlikely, unfortunately, that we will succeed in getting every single smoker who works in a high-risk environment to quit smoking. However, widespread smoking cessation remains the ideal solution for dramatically reducing cancer among high-risk workers.

We believe that the kind of monitoring and follow-up of workers at high risk that is proposed in this bill is reasonable. We believe it would not be a high cost item for employers, and we believe it would place the proper responsibility for action with the employee, and would, Mr. Chairman, have the potential for saving many thousands of lives from cancer over time, that being the most important goal.

The American Cancer Society has a special interest in the objectives of this legislation. Much of the information gained over the past 20 years about workplace carcinogens and other toxic substances has been realized through two of the National Society's long-term human epidemiologic studies, "The Environmental Cancer Research Project" and its "Cancer Prevention Studies I and II." These and other studies have provided the vital human epidemiologic data regarding such substances as asbestos, vinyl chloride, kepone, PCBs and others.

We have gained a great deal of knowledge in the past two decades about the effects on humans of known and/or suspected carcinogens in the workplace. That was the first step. We now have an opportunity to take the necessary second step to put that new knowledge to work in saving the lives of the people who make this country function.

In the interest of time, Mr. Chairman, let me summarize by saying the American Cancer Society believes that S. 79 is a good bill. Its introduction represents a reasonable step by the Congress to address an important public health issue. As we interpret it, S. 79 recognizes both the need of the employee to know and the need of the employer to inform, while at the same time it would provide a vital new element in protecting the health and life of the American worker, who remains one of our nation's greatest national and natural resources.

I appreciate this opportunity to testify and would be happy to answer questions at the appropriate time.

Senator METZENBAUM. Thank you very much, Dr. Seffrin.

[The prepared statement of Dr. Seffrin and responses to questions submitted by Senator Hatch follow:]

AMERICAN
CANCER
SOCIETY®

TESTIMONY OF

JOHN R. SEFFRIN, Ph.D.

PROFESSOR AND CHAIRMAN
DEPARTMENT OF APPLIED HEALTH SCIENCE
INDIANA UNIVERSITY
BLOOMINGTON, INDIANA

AND

VICE PRESIDENT
NATIONAL BOARD OF DIRECTORS
AMERICAN CANCER SOCIETY

ON THE BEHALF OF THE

AMERICAN CANCER SOCIETY

REGARDING S.79

"HIGH RISK OCCUPATIONAL DISEASE
NOTIFICATION AND PREVENTION ACT OF 1987"

BEFORE THE

SUBCOMMITTEE ON LABOR
COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

FEBRUARY 24, 1987

I am John R. Seffrin. I am Professor and Chairman of the Department of Applied Health Science at Indiana University and also Director of the Center for Health and Safety Studies. I am here today representing the American Cancer Society as a long-time volunteer, and Vice-President of the Society's National Board of Directors. I would like to comment on S. 79, "The High Risk Occupational Disease Notification and Prevention Act of 1987".

In March 1986, the American Cancer Society (ACS) Board Directors approved the following resolution regarding similar legislation which was before the Congress last year:

> RESOLVED: The American Cancer Society supports the intent of S.2050 and H.R. 1309 and will work with Members of Congress to secure legislation to prevent and modify risks of occupationally induced cancer.

That action was consistent with a policy statement adopted by the Society's Board of Directors in 1980, which, in part, reads:

> RESOLVED: The American Cancer Society believes that where there is information that chemicals or other industrial agents used in the workplace are known to cause cancer, or are scientifically suspect of causing cancer in humans, the employee has a right to such information.

We believe that Senator Metzenbaum has again presented a realistic and practical bill, which if enacted, would address a very important need, namely, the establishment of a non-threatening system for monitoring workers in business and industrial situations who are, by the very nature of their work, exposed to substances known or suspected of being toxic. By being monitored in a systematic and standardized way, those who may be receiving unacceptably high exposure to these toxic substances can be identified, hopefully before it is too late to reverse the situation, and measures can be taken by the worker and management to reduce the exposure.

Mr. Chairman, primary prevention of cancer, of course, is the most desirable means of reducing cancer morbidity and mortality. Not only does the primary prevention of cancer preserve the quality of life of the worker, but of course, it obviates the need for expensive treatment of a life-threatening disease.

The American Cancer Society's purpose is to do everything possible to eliminate cancer as a serious threat to human health. Our principal efforts are through education, research and service to the cancer patient. We support the intent of S. 79 because it directly addresses the objective of our 1980 position and it addresses a very important issue: acknowledging, understanding, and acting on some of the vast range of knowledge we have gained in recent years about known, and suspected causes of cancer.

We would not expect that enactment of this or any other legislation would result in elimination of workers' cancer risk. We know that cigarette smoking dramatically enhances the carcinogenic effects of many toxic agents, and it is still unlikely that we will succeed in getting every smoker who works in a high-risk environment to quit smoking. However, wide spread smoking cessation remains the ideal solution among the high-risk workers.

We believe that the kind of monitoring and follow-up of workers at high-risk that is proposed in this bill is reasonable; we believe it would not be a high cost item for employers; and would place proper responsibility for action with the employee; and would, Mr. Chairman, have the potential for saving many thousands of lives from cancer over time.

The American Cancer Society has a special interest in the objectives of this legislation. Much of the information gained over the past 20 years about workplace carcinogens and other toxic substances has been realized through two of the Society's long-term studies, "The Environmental Cancer Research Project," and its "Cancer Prevention Study." These and other studies have provided the vital human epidemiological data regarding such substances as asbestos, vinyl chloride, kepone, PCB's and others.

We have gained a great deal of knowledge in the past two decades about the effects on humans of known and suspected carcinogens in the workplace. That was the first step. We now have an opportunity to take the necessary second step to put that new knowledge to work in saving the lives of the people who make this country function.

A review of S. 79 reveals that it is a considered proposal which provides a realistic vehicle to inform and thus protect workers: it appears to be fair, and therefore, has a good chance of being acceptable to both business and industry. Its purpose, as we interpret it, is to promote the prevention and early detection of occupational disease through a system of identifying, notifying, and counseling workers at risk, while concomitantly encouraging the provision of facilities needed for proper diagnosis and treatment.

We already know that some hazardous substances can cause health problems. In recent years, the Occupational Safety and Health Administration (OSHA) has issued permanent standards setting permissible exposure limits for more than 20 toxic substances.

Seven years ago, the American Cancer Society called attention to the right of workers to be informed about carcinogenic substances to which they may be exposed in their workplace, when such knowledge exists. S. 79 goes beyond our general suggestion of that time -- it promises to be effective by focusing precisely on those workers who need the knowledge most, and those who are at highest risk by virtue of their exposure to the heaviest concentrations of toxic agents.

Current federal law provides that medical records be kept by employers for workers at high risk. Current law also requires that worker populations be advised through general notification -- such as notices on bulletin boards -- that they should monitor their health status through their physicians, or other medical care and social service professionals. While we believe that existing law is on the right track, it has not been fully effective, precisely because it is general and not as focused as S. 79 would be.

A key element of the bill is the proposed enhancement of regional health care centers, whereby local health care professionals would be provided with training to do the actual surveillance of those persons at high risk.

Mr. Chairman, the American Cancer Society believes that S. 79 is a good bill. Its introduction represents a reasonable step by the Congress to address an important public health issue. As we interpret it, it recognizes the concerns of both business and industry, while at the same time, it would provide a vital new element in protecting the health and lives of the American worker -- who remains one of our greatest national, as well as natural resources.

The job of the American Cancer Society is to eliminate cancer through prevention, early diagnosis, service to the cancer patient, and research. While we claim no expertise in the area of compliance, liability or regulation, we believe that enactment of this type of legislation would significantly reduce, over time, both the incidence and death rate of cancer.

Thank you very much for the opportunity to appear before you. I would be pleased to answer any questions.

AMERICAN
CANCER
SOCIETY NATIONAL OFFICE

March 17, 1987

The Honorable Howard M. Metzenbaum
United States Senate
SR-140 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Metzenbaum:

As per your letter dated March 2, 1987, I would like to provide you with answers submitted to me by Senator Orrin Hatch.

If you or Senator Hatch have any questions, please feel free to contact John H. Madigan, Jr., National Director of Public Affairs in the Washington, D.C. office at (202) 546-4011.

Sincerely,

John A. Seffrin

John A. Seffrin, Ph.D.
Vice President
National Board of Directors
American Cancer Society

Enclosure

AMERICAN CANCER SOCIETY, INC.
90 PARK AVENUE, NEW YORK, N.Y. 10016 • 212-599-8200

QUESTION 1.

You mentioned that prevention is the most desirable means of reducing cancer morbidity and mortality. I would agree with that statement. I myself have spent a major part of my political career working for health promotion and disease prevention. The best way to prevent disease is to prevent exposure, but that is not what S.79 does. S.79 is aimed at medical follow-up after exposure has taken place. My question is this -- how effective is intervention at that point?

Answer 1.

While prevention is the ideal way in which to reduce cancer deaths, early detection continues to be a very important way to reduce unnecessary cancer mortality. Intervention to identify and monitor workers at unusual or high risk is extremely important to any nationwide initiative to reduce occupationally induced cancer morbidity and mortality. The American Cancer Society estimates that over 165,000 Americans will die in 1987, just because their disease was detected too late. Obviously, a systematic intervention effort within the America's workforce to monitor workers and to detect cancer early would result in an annual net reduction in lives lost to cancer. Moreover, a monitoring and notification effort would provide an opportunity for education, and in some cases, alterations in the hazard level. In other words, some disease could be prevented altogether, while others could be diagnosed earlier; thus, in aggregate, many more lives would be saved.

QUESTION 2.

I also agree with your statement that wide-spread smoking cessation remains the ideal solution among the high-risk workers. Since this legislation deals with who should pay for health care after exposure has taken place, what you do think about requiring those workers who continue to expose themselves to cigarette smoke to pay for that portion of their health care cost?

Answer 2.

I would have no problem with requiring smokers to pay their fair share of the excessive health-care costs incurred due to their particular lifestyles.

Consistent with this, however, would be the same logic applied to industry. As I stated in the testimony, we have no expertise in the liability area, and are not competent to comment on that. But I would have no objection to workers paying their fair share of the costs of self-induced disease, if employers would pay their fair share of excess morbidity and mortality due to hazards resulting from workplace exposure to carcinogens and other toxic substances.

QUESTION 3.

If you exclude cigarette smoking, how many lives can we save through medical follow-up after the exposure has taken place?

Answer 3.

I can provide no specific number as to how many lives can be saved independent of smoking cessation. However, I can assert that more lives could be saved than presently are being saved, if we had a system to monitor and detect occupationally induced diseases early.

QUESTION 4.

You state that the American Cancer Society believes that this legislation would not be a high cost item for employers. How much do you think this legislation will cost employers per year or per employee? Could you break that down into costs for notification, costs for medical screening, costs for medical follow-up, and costs for health care? Do you have a position on who should pay for those costs?

Answer 4.

No analyses have been done by the American Cancer Society to determine that exact cost to industry for monitoring and early notification of workers at high risk. However, literature on the subject of cost-effectiveness would suggest that the notificcation and monitoring of high risk workers would be far less expensive than the medical care costs incurred through the treatment of late or end-stage disease.

QUESTION 5.

S.79 requires the notification of a minimum of 100,000 workers a year. Do you think the Risk Assessment Board should be forced to notify a given number of workers or should the number of workers notified be based on scientific evidence?

Answer 5.

I believe that the Risk Assessment Board should be duty-bound to notify all workers who experience unusual or high risk from exposure to occupational toxins and carcinogens. This exact at-risk group should be identified on a scientific basis. If at the outset of the early notification effort it is not possible to notify every worker at high risk, then ethics would dictate that as many workers be notified as resources permit.

Senator **Metzenbaum**. Dr. Merchant, representing the American Lung Association and the American Thoracic Society.

Dr. **Merchant**. Mr. Chairman and members of the Subcommittee, I am James A Merchant, Professor of Preventive Medicine and Internal Medicine at the University of Iowa. From 1975 through 1982, I was a Commissioned Officer in the U.S. Public Health Service and directed NIOSH's Division of Respiratory Disease Studies and the Appalachian Laboratory for Occupational Safety and Health, in Morgantown, West Virginia.

I appear before you today in behalf of the American Lung Association and its medical section, the American Thoracic Society.

Workers in the United States face a myriad of health risks from occupational and environmental exposures to hazardous substances. The lung is both a target organ and a portal of entry for toxic substances. The likelihood of toxic exposure is high.

For example, an estimated 1.2 million workers each year are potentially exposed to silica dust alone. In 1980, the Department of Labor estimated that job-related respiratory disease accounted for at least 65,000 acute and chronic disabilities and 25,000 deaths each year.

It is well-accepted, however, that there is less accurate information on occupational illnesses than injuries and that the Bureau of Labor Statistics' annual survey underestimates the magnitude of occupational illnesses.

There can be no doubt that workers would benefit from more accurate and dispassionate characterization of the occupational risks that they face and from a broader dissemination of information regarding these risks.

The often inadequate communication between those who generate and interpret risk assessment data, those who are responsible for public health decision and policymaking, and those who must consider whether to assume these risks has resulted in an incomplete and often distorted assessment of health risks in the workplace.

The American Lung Association has long supported the education of workers regarding workplace health hazards and supports the concept of identifying and notifying workers at high risk of developing occupational diseases.

Our comments today will focus on three components central to the identification and notification of workers at high risk as provided for in S. 79. These include the role of the Risk Assessment Board and the methodology for identifying populations at risk; the benefits of medical surveillance for the identified workers, and the improvements to the database to be derived from research which would be fostered by this Act.

The framers of S. 79 recognize that the determination of a particular risk requires careful evaluation of the extent and quality of the science supporting it and that this process requires special expertise.

The establishment of a National Risk Assessment Board is a reasonable approach which provides a sound basis for rational decisionmaking regarding the identification of populations of workers at risk. Particularly in the case of long exposure, long latency diseases such as occupational lung disease and cancer, judgments must be made to determine whether workplace exposures are associated with or cause the disease. Importantly, if determined elevations in risk are to trigger a process of identification and notification, scientific studies must be examined for the level of confidence that an observed risk is indeed elevated.

The credibility of the Risk Assessment Board depends on a number of facts. It must be comprised of respected scientists who are experienced in occupational health issues. Through its composition, the Board must be balanced in its scientific perspective, in both fact and public perception. Board members should represent a range of disciplines engaged in occupational disease research and treatment. An occupational qualification should be included for the epidemiologist, toxicologist, and physician.

Further, we suggest that the size of the Board be expanded to include representatives from outside the Public Health Service, representing the important discipline of occupational biostatistics.

A principal benefit of this legislation is provision of employee notification and counseling. Counseling information should stress the importance for workers to enter medical surveillance programs. The American Lung Association has long supported workplace medical surveillance programs.

In 1982, the American Thoracic Society issued a scientific statement entitled, "Surveillance for Respiratory Disease Hazards in the Occupational Setting" detailing the components of an effective medical surveillance system for occupational respiratory diseases.

The ability to alter adverse health outcomes of workers exposed to occupational hazards depends in large part on early recognition and intervention. Medical surveillance programs also address the opportunity to address the significant cofactors and multifactorial occupational diseases such as cancer and chronic obstructive lung disease. One obvious and important cofactor for occupational lung disease and cancer is cigarette smoking.

Intervention in the form of smoking cessation can greatly reduce the risk of disease manifestation and carcinogens.

Senator METZENBAUM. Excuse me, Dr. Merchant; can you wind up, please?

Dr. MERCHANT. Yes. While information is unavailable regarding the quantification of monetary benefits of medical surveillance programs, early detection and the implementation of intervention strategies will in time reduce both human and dollar costs of occupational exposures. The long-term benefit of this legislation should be viewed as an investment in the future.

Too little has been done to date to promote and protect the health of the American work force. This legislation should strengthen current research programs and remedy important programmatic gaps. As the Subcommittee proceeds with its deliberations, the American Lung Association will continue to offer its scientific and medical expertise to assist you in assessing these complex health issues.

Thank you for the opportunity to comment.

Senator METZENBAUM. Thank you very much, and thanks to each of the panelists.

[The prepared statement of Dr. Merchant with attachments and responses to questions submitted by Senator Hatch follow:]

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AMERICAN LUNG ASSOCIATION
The Christmas Seal People ®

STATEMENT OF

JAMES A. MERCHANT, M.D., Dr. P.H.

ON BEHALF OF

THE AMERICAN LUNG ASSOCIATION AND
THE AMERICAN THORACIC SOCIETY

TO THE

SUBCOMMITTEE ON LABOR
COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

RE: THE HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION
AND PREVENTION ACT OF 1987

FEBRUARY 24, 1987

National Headquarters 1740 Broadway, New York, N.Y. 10019-4374 • James A. Swomley, Managing Director

Mr. Chairman, Members of the Subcommittee,

I am James A. Merchant and am Professor of Preventive Medicine and Occupational Health and Director of the Institute of Agricultural Medicine and Occupational Health at the College of Medicine, University of Iowa. From 1975 to 1982, I directed the National Institute for Occupational Safety and Health (NIOSH) Occupational Respiratory Disease Research Division at the Appalachian Laboratory for Occupational Safety and Health in Morgantown, West Virginia. I appear before you today on behalf of the American Lung Association and its medical section, the American Thoracic Society.

Workers in the United States face an ever increasing health problem from occupational and environmental exposure to toxic substances. The lung is both a target organ and a portal of entry for toxic substances. The likelihood of toxic exposure is high--for example, an estimated 1.2 million workers each year are potentially exposed to silica dust alone. In 1980, the Department of Labor estimated that job-related respiratory diseases account for at least 65,000 acute and chronic disabilities and 25,000 deaths each year. It is well accepted however, that there is less accurate information on occupational illnesses than injuries and that the Bureau of Labor Standards annual survey underestimates the magnitude of occupational illnesses. This underestimation occurs because many of the occupational illnesses are indistinguishable from non-occupational diseases, because they often become manifest only after a long latency period, and because of a general lack of recognition of the occupational causes of many diseases.

There can be no doubt that workers would benefit from more accurate and dispassionate characterization of the occupational risks that each faces, and from broader dissemination of information regarding these risks. The often inadequate communication between those who generate and interpret risk assessment data, those who are responsible for public health policy decisionmaking, and those who must consider whether to assume these risks, has resulted in an incomplete perception of risks in the workplace.

The American Lung Association has long supported the education of workers regarding workplace health hazards and supports the concept of identifying and notifying workers at high risk of developing occupational disease. Our comments today will focus on three components central to the identification and notification of workers at high risk as provided for in S. 79, the High Risk Occupational Disease Notification and Prevention Act. These include the role of the Risk Assessment Board and the methodology for identifying populations at risk of disease, the benefits of medical surveillance for the identified workers, and the improvements to the data base to be derived from the research which would be fostered by this Act.

There are problems in achieving the desired objective of identification and notification of "at-risk workers". The scientific data base on occupational risks, while at times substantial but underutilized, is often incomplete, or worse, absent. The nature of the hazard may not be fully understood, or the perceptions of it distorted. The epidemiologic and statistical methods of determining elevated risk may be difficult to understand, but are cirtical to our understanding of the potential hazard.

The framers of S. 79 recognize that the determination of a particular risk requires careful evaluation of the extent and quality of the science supporting it, and that this process requires special expertise. The establishment of a National Risk Assessment Board is a reasonable approacn which provides a sound basis for rational decision-making regarding the identification of populations of workers at risk. Particularly in the case of long exposure, long latency diseases such as occupational lung diseases, judgements must be made to determine whether workplace exposures are associated with or caused the disease. Importantly, if determined elevations in risk are to trigger a process of identification and notification, scientific studies must be examined for the level of confidence that an observed risk is, indeed, elevated.

One of the difficulties in implementing this legislation will be the lack of acceptable environmental data on employee exposures in some instances. This gap in data will make it more difficult to identify some subpopulations of workers who are at particular risk. However, this concern should not be used to detract from the importance of proceeding with this legislation. Rather, it should be recognized as an issue which the Risk Assessment Board should address by consulting with the industrial hygine and environmental assessment communities for specific expertise regarding its resolution.

The credibility of the Risk Assessment Board depends on a number of factors. It must be comprised of respected scientists who are experienced in occupational health issues. Through its composition, the Board must be balanced in its scientific perspective, in both fact and public perception. Board members should represent a range of disciplines engaged in occupational disease research and treatment. The occupational qualification should be included for the epidemiologist, toxicologist, and physician. Further, we suggest that of the size of the Board be expanded to include representatives from outside the Public Health Service and to include the important discipline of occupational biostatistics.

A principle benefit of this legislation is provision for employee notification and counseling. Counseling information should stress the importance for workers to enter medical surveillance programs. The American Lung Association has long supported workplace medical surveillance programs. In 1982, the American Thoracic Society issued a scientific statement, "Surveillance for Respiratory Hazards in the Occupational Setting", detailing the components of effective medical surveillance for occupational respiratory disease. A copy is attached for the Subcommittee's information.

The ability to alter adverse health outcomes of workers exposed to occupational hazards depends in large part on early recognition and intervention. Medical surveillance programs also allow the opportunity to address the significant cofactors in the multifactorial occupational diseases such as cancer and Chronic Obstructive Lung Disease. One obvious and important cofactor for occupational lung disease is cigarette smoking. Intervention in the form of smoking cessation can greatly reduce the risk of disease manifestation and or progression. An example is asbestos-related diseases and the multiplier effect of smoking with occupational exposures. Smoking cessation significantly reduces the risk of developing disease in this population of workers.

While data is unavailable regarding the quantification of the monetary benefits of medical surveillance programs, early detection and the implementation of intervention strategies will reduce both the human and dollar costs of occupational exposures. The long term benefit of this legislation can be portrayed as an investment in the future.

Our final comments address the research and training activity provided for in S. 79. An indirect benefit of this legislation will be the extablishment of employee exposure registries. Such registries will be of enormous benefit to epidemiologic research in surveillance of occupational diseases. Directly and critical to the accomplishment of the goals of this legislation--the identification and notification of workers at high risk--is the enlargement of a high quality scientific data base. The extent of the current federal research effort in this important area of public health is regrettably inadequate. Important contributions have come from many biomedical disciplines extending beyond the traditional public health community. The research program envisioned by the framers of S. 79 should encourage a range of disciplines to work collaboratively to increase our fundamental knowledge regarding the determinants of occupational diseases. Such broad-based research is the most reliable path to the prevention of these diseases. As such, the research program should be developed and implemented by a federal agency, such as NIOSH, with a broader scope of concern than the Risk Assessment Board. The limitations on the available data base upon which to make risk assessments can only be overcome by strengthening the support of relevant biomedical research and training activity.

Too little has been done to date to promote and protect the health of the American workforce. This legislation should be seen as strengthening current programs and remedying important programmatic gaps. As the Subcommittee proceeds with its deliberations, the American Lung Association will continue to offer its scientific and medical expertise to assist you in assessing these complex health issues.

Thank you for this opportunity to provide comment.

SURVEILLANCE FOR RESPIRATORY HAZARDS IN THE OCCUPATIONAL SETTING

American Thoracic Society, medical section of American Lung Association

This official ATS statement was adopted by the ATS Board of Directors, June 1982.

Introduction

Occupational respiratory diseases are an important cause of disability, days lost from employment, and death (1, 2). Because of this, there has been concern for the need, expectations for the provisions, and demands for the initiation of occupational health surveillance programs by society, by employed persons, and by governmental agencies. While early programs were limited in scope, present emphasis has enlarged the components and services of an occupational health program. Furthermore, an effective program requires the skills of various professionals who are trained or experienced in such disciplines as medicine, industrial hygiene, toxicology, epidemiology/biostatistics, nursing, and safety engineering (2). An organizational structure is necessary to assure that the top echelons of management are aware and informed of all significant occupational health concerns so that appropriate corrective action can be taken when necessary. At the same time, procedures for preserving employee confidentiality must be administered. Records that are developed should include medical and industrial hygiene information and data necessary for epidemiologic review that are pertinent to workplace exposures.

This document will list and discuss those components and services that are considered a necessary or essential part of an occupational pulmonary surveillance program. By surveillance, it is meant the continuing scrutiny of all aspects involved in the occurrence and/or development of occupational pulmonary disease that are pertinent to effective control of disease (3). Surveillance includes collection, collation, and analysis of relevant data, as well as reporting to persons responsible for controlling hazards in the workplace.

Components of an occupational respiratory disease surveillance program are shown in table 1. It is apparent that of the components listed, only one relates to medical evaluation of the health status of employees. This can be accomplished by using appropriate screening tests. By screening, it is meant the presumptive identification of unrecognized disease or defect by the application of tests, examinations, or other procedures that can be applied rapidly to sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be diagnostic. Persons with positive or suspicious findings must be referred for diagnosis and necessary treatment (4).

Principles Underlying Screening Programs

Screening may have one of several aims (5). It may be undertaken as part of an epidemiologic survey to determine the frequency or natural history of a condition (i.e., Framingham study of coronary heart disease), prevention of a contagious disease and protection of the public's health (i.e., mass chest X-rays for detecting tuberculosis), or the detection of disease or precursors of disease, as a guide to the medical care of individuals (i.e., occupational respiratory screening programs).

In undertaking an occupational respiratory screening program, the presumption is made that not only are the screening methods reliable, but treatment or remedy is possible and will be made available to those who require it. In addition, it is essential to insure that the screening will make better use of limited resources than competing medical measures (5). The implication of these requirements for screening procedures are reflected in the following list of principles (6, 7):

1. The condition sought should be an important health problem.
2. There should be an accepted treatment for individuals with recognized disease.
3. Facilities for diagnosis and treatment should be available.
4. There should be a recognizable latent or early symptomatic stage.
5. The natural history of the condition, including development from latent to declared disease, should be adequately understood or studied as a result of the findings.
6. There should be a suitable screening test or examination for detecting the disease at the latent or early stage.
7. The test should be acceptable to the population.
8. There should be previously agreed upon criteria or policy to identify and classify those with injury or disease and whom to treat as patients.
9. Further diagnostic study and/or treatment (if known) of patient revealed by the screening programs should be made available.
10. The cost of case-finding, including diagnosis and treatment of patients diagnosed should be economically balanced in relation to possible expenditure on medical care as a whole.
11. Caution should be exercised to assure that the benefits accruing to the true positives outweigh the possible harm which might be done to those falsely identified as a positive diagnosis.
12. Case finding should be a continuous process—not a "once and for all" project.

Purposes For Conducting Surveillance in Industry

The primary reasons for initiating and conducting surveillance programs in industry are:

1. to detect respiratory impairment of disease prior to placement;
2. to determine the nature and extent of both occupationally related and naturally occurring respiratory diseases in the workforce;
3. to conduct epidemiologic studies related to hazards known or thought to be present in the workplace;
4. to produce data, which, when considered along with other evidence, will help to determine standards for limiting exposures in order to prevent injury or disease.

Baseline and ongoing surveillance in industry should be programmed to proceed in a step-wide fashion (table 2).

Screening Tests to Use in a Surveillance Program

Standardized procedures have been developed for study of large population groups (8). Performed initially or cross-sectionally, screening studies may determine prevalence of symptoms, status of pulmonary function, and similar situations at one point in time. Repeated, using the same population, at a later point in time, they serve as prospective or longitudinal studies and can then determine incidence of disease or give information regarding progression or development of illness. Data derived from screening studies differ from those required for clinical studies that are diagnostic and directed towards individuals rather than groups.

Abnormalities identified by screening must be confirmed and then referred for diagnostic studies in order to determine their relationship to the work environment and their true significance. The various tests/parameters that may be used in pulmonary screening in an occupational setting include the history, physical examination, spirometry, chest X-ray, and other tests. Some of these have been discussed in detail previously (8).

History and Physical Examination

Employees should have a complete health

Reprinted from American Review of Respiratory Disease, Vol 126, No 5, November 1982

TABLE 1

COMPONENTS OF OCCUPATIONAL RESPIRATORY DISEASE SURVEILLANCE PROGRAM

Regular evaluation of employee health status.
Education of employees.
Assist management.
Proper maintenance of medical records.
Employee evaluation for respiratory protective devices.
Initiation/interpretation of government regulations.
Insure proper training and performance of personnel and surveillance equipment.
Epidemiologic evaluation of workplace/employees.
Industrial hygiene evaluation of work environment.

history taken upon employment. This history will serve as a baseline against which to measure changes occurring during the employment period. The respiratory questionnaire is an important component of this complete health history. In the early 1950s, the basic concepts were developed in England by Fletcher (9). After extensive studies, the Medical Research Council (MRC) accepted a standard questionnaire in 1960 with a revision in 1976. It has been translated into many languages and used worldwide (10). For the United States, the American Thoracic Society (ATS) Committee for Standardization of Epidemiological Methods has published a similar questionnaire (11). For the industrial setting, the ATS questionnaire can be applied appropriately. Three features of the questionnaire are especially important: degree of dyspnea, amount of cough and sputum, and amount of cigarette smoking.

Breathlessness is often the principal manifestation of pulmonary impairment. Causes of dyspnea are complex and still remain poorly understood, and a person's response to questions concerning shortness of breath are variable. These responses may be influenced by factors unrelated to lung disease such as difficulty of verbal expression, socioeconomic factors, and educational background. These considerations are an important element in dyspnea evaluation. However, for the most part in the industrial setting, the degree of dyspnea can be determined with specific questions. For example, the following descriptions are taken from the MRC and ATS questionnaires (9, 11):

Grade	*Degree*	
0	None	Not troubled with breathlessness except with strenuous exercise.
1	Slight	Troubled by shortness of breath when hurrying on the level or walking up a slight hill.
2	Moderate	Walks slower than people of the same age on the level because of breathlessness or has to stop for breath when walking at own pace on the level.
3	Severe	Stops for breath after walking about 100 yards or after a few minutes on the level.
4	Very severe	Too breathless to leave the house or breathless when dressing or undressing.

The amount of cough should be determined: (*1*) none or occasionally with colds; (*2*) mild, an occasional morning cough, (*3*) moderate, four to six times daily; and (*4*) severe, morning and throughout the day for three consecutive months or more. Sputum production should be similarly categorized: (*1*) none; (*2*) occasional morning sputum; (*3*) moderate, twice a day, four or more days of the week; (*4*) severe, morning and throughout the day for three consecutive months or more. Importantly, the duration of cough and sputum should be noted, especially if these symptoms occur at least three consecutive months over two or more years. The answers to these questions can be used to determine the presence of "chronic bronchitis," which is arbitrarily defined as a productive cough for most days for a minimum of three consecutive months for two or more years (12).

Concerning cigarette smoking, subjects should be classified as nonsmokers if they smoke less than 20 packs of cigarettes or 12 ounces of tobacco in a lifetime or less than one cigarette a day for one year. Information from smokers include age started and, if appropriate, stopped smoking. The amount smoked should be categorized as packs per day, e.g., less than one-half, one and one-half, and two or more.

TABLE 2

PLAN FOR ONGOING SURVEILLANCE

Level	Site	Employees
I. No hazard thought to be present	I. Catalogue and review of materials and processes.	I. (a) Questionnaires (b) Simple PFT (1) FVC (2) FEV, (c) Baseline CXR
II. Suspicion of hazard present	Above plus II. Area and personal monitoring by industrial hygienist	Above plus II. "Hands-on" physical examination and review by a physician to consider further tests
III. Known hazard present	Above plus III. (a) administrative controls; (b) engineering changes; (c) individual protective equipment	Above plus III. Special testing based on hazard present

Apart from these three important questions, several others are helpful in the industrial setting. The presence of wheezing should be categorized as slight if it occurs only with colds or severe if wheezing is present daily. In selected industrial settings, the occurrence of wheezing or productive cough on Mondays or after returning to work from holidays may be important symptoms related to occupational asthma. The occurrence of hemoptysis whether slight with blood streaked sputum or severe should be recorded.

Information concerning nonpulmonary disease should also be recorded. These include cardiac disorders, hypertension, diabetes, peptic ulcer disease, or other gastrointestinal abnormalities, neoplastic disease, renal disease, or rhematologic or neurologic disorders. Type and dosages of required medication should be listed as well. In addition, questions concerning past pulmonary illness should be specifically noted. These include chest illness during the previous three years that have the subject off work, indoors, at home, or in bed. Specific pulmonary diseases include pneumonia, asthma, bronchitis, emphysema, or tuberculosis. Similar pulmonary diseases occurring in the family should also be listed. There are several other detailed questions concerning symptoms and cigarette use that are available in the ATS publication (11). These questions should be used according to specific industrial environments.

Bias is an important concern of respiratory questionnaires. For example, observer bias was initially a problem in the 1950s, but this can be minimized by properly training personnel (10). Questionnaire modification is another source of bias with minor alterations in questions concerning symptoms reducing reliability. In industrial surveillance programs, the mode of administration is an important consideration. The early questionnaires were developed for administration by an interview but they have now been adapted for self-completion (11). Fortunately, the self-completed type of questionnaire has not created an additional bias. There has been a high level of agreement between responses to the dyspnea, cough, and phlegm questions of an administered MRC questionnaire to responses of a similarly worded ATS questionnaire that was self-completed (10).

Occupational History

Another essential component is a complete occupational history. For the purpose of surveillance, two sources of work exposure history become important:

(*1*) *Prior work history*—Occupational

exposures that resulted during previous employment wherein the employee is the primary source of information, and further data usually is obtainable only by the employee requesting a release of any available records of prior employers.

(2) Current employer work history—Occupational exposures can often be imputed from personnel records where past and current environmental surveys are linked to job titles for given work areas, where individuals in such areas can be identified for given blocks of time, and where survey data can be reasonably attributed to all identified employees in all time blocks.

From a practical viewpoint there are reasonable limits that one expects to achieve from both of these sources. From most job applicants one can expect a person to be able to complete an employment form with basic information on job titles, employer's name and address, years of service in each job title, and dates of transfer or termination. By a careful review of such a self-completed employment form, a skilled interviewer can often determine whether or not any prior employers required medical surveillance, whether any inhalation hazards were reported to the employees in the work area, whether any specific exposure controls were evident to persons assigned in the area, and whether the interviewee experienced or reported any occupational respiratory disease conditions during employment in the area. The level of detail and accuracy of such an occupational history by interview probably varies from one job applicant to the next, and certainly as one attempts to retrieve such information over periods of ten or more years prior to the current date, recall becomes less reliable. One should balance the use of this information from the standpoint of a current medical surveillance decision against such reliability questions; hence, when placing a worker with a history of prior work exposures that may have included an occupational respiratory disease risk, the physician should focus primarily on the patient's current respiratory health status and require medical surveillance only where the current job assignment would so indicate. One can defer a final decision on medical surveillance and attempt to retrieve fuller details from prior employers where the level and type of the prior exposures would appear to be more important to the patient's health, especially where the current respiratory health status is abnormal or borderline by routine screening tests.

Each employee should have a reasonably complete job assignment history maintained by his current employer. Such information becomes more useful to the medical staff if specific exposure details are recorded in each medical folder and updated periodically. This seemingly simple ongoing exposure history is more difficult to implement than one would expect; however, one cannot assemble a roster of candidates for medical surveillance without knowing when and who are transferred in and out of respiratory hazard areas. Given information that an employee has been assigned to such an area and that surveillance has been triggered, the sources of environmental data include both independent sources such as in survey records as well as a current exposure history from the employee. Comparisons of such different sources is often helpful; and when one is obtaining a patient history, one can inquire into avocational exposures or moonlight job activities as well.

For purposes of cross-checking, two additional occupational history tools should be used to supplement the chronological exposure histories:

(1) Specific Agent Questionnaire—A listing of specific inhalants that are prominent causes of occupational respiratory disease.

(2) Specific Occupational or Industry Group Questionnaire—A listing of job situations where occupational respiratory disease incidence is generally regarded or suspected to be higher than the average rate.

Physical Examination

The physical examination is important for the detection of finger clubbing, wheezes, and crackles (13, 14). Additional information is also helpful such as a general description of the patient, presence of cyanosis, or pedal edema, description of the patient's breathing, extent of chest excursion, intensity of breath sounds heard, and results of cardiac, abdominal, neurologic and joint examinations.

The detailed respiratory questionnaire as well as the physical examination should be performed for pre-employment or preplacement, transfer into hazardous area from previous employment, and transfer out or retirement. Questionnaires for pre-employment, transfer in or out, and retirement should be performed by an interviewer, while the periodic questionnaires may be self-administered.

Spirometry

Spirometry Criteria

Persons employed in hazardous occupational settings should have a spirogram performed. The minimum requirements should be the measurement of FVC and FEV_1 (15). Spirometry should be conducted using the techniques, criteria, and instrumentation recommended by the Snowbird Workshop (16). Spirometers have been evaluated for compliance with the Snowbird criteria and results reported for devices available in 1977 (17, 18). As stated by the Snowbird Workshop, "At least 3 acceptable tests are required to ensure maximal effort and cooperation are obtained . . ." This requirement has subsequently been verified (19). Recent studies (20) have shown that selections of a single "best test" by taking the spirogram with the largest sum of FVC and FEV_1 allows all measurements to be made on a single waveform and does not make a significant difference with normal or diseased subjects.

Performance of spirometry is critically dependent on subject's performance. Technicians should be well trained, motivated and able to demonstrate an acceptable performance in the actual situation. The training requirements suggested by CORD and NIOSH are recommended (21, 22).

Results Evaluation

Once the spirometric tests have been performed with appropriate technique, instruments, and technical staff, then the results need to be evaluated (23). Because measure of ventilatory function are dependent on age, height, sex, race, and other factors, all these parameters should be considered in any interpretation. One can evaluate spirometric tests by (*1*) using the subject as their own control, or (*2*) comparing the subject with a reference or "normal" population. Using the subject as their own control gives better sensitivity than comparison with normal population. The coefficient of variation within subject is 3 to 6% for FVC, whereas it is near 14% with a population. Because the normal yearly decrement in ventilation is small (approximately 25 ml/yr for FVC), to detect abnormality, the decrement must either be large or the subject must be followed for a long time. Adequate longitudinal studies have not been done; therefore it is currently necessary to compare a subject's observed values with a reference population.

Normal Values

Prediction equations for determining normal values have been derived by many investigators (24–27, 34). Comparison of the FVC and FEV_1 reference values has recently been reported (28).

The Intermountain Thoracic Society (ITS) has formalized interpretation criteria (29). There has been recent interest in the variability of interpretation (30, 31). Based on the data of Crapo, the suggested lower limit of "normal" is a fixed decrement from the predicted value (e.g., for males FVC = 1.102 liters; FEV_1 = 0.831 liters). The subtraction of just one number for all adult males for FVC is justified because the 95% confidence limit range is so small. Recent reanalysis of the 1971 Morris-Oregon survey data has provided results nearly identical to the study of Crapo and coworkers (27, 28, 32).

Obstructive lung diseases should be classified by either using the FEV_1/FVC ratio or looking at predicted values.

Chest X-ray

Radiologic surveillance for respiratory hazards in the occupational setting must include consideration of the need, type, and frequency of surveillance, minimal standards for equipment and filming, and the method of interpretation and recording of the information for patient care, record keeping, and epidemiology. Although data have shown that routine surveillance for respiratory disease, specifically, tuberculosis and carcinoma, in the asymptomatic population has been nonproductive, routine surveillance in those exposed to a respiratory hazard is essential (33-35).

Recommended surveillance studies of those with known or potential respiratory hazards:

1. Routine chest X-ray, preplacement. This establishes a baseline for those without respiratory disease and will demonstrate some in whom preexisting disease would preclude exposure.
2. Routine PA screening films at two to five year intervals in asymptomatic individuals, depending on specific hazard. Discernible change in the radiograph in those without symptoms or signs of respiratory disease at more frequent intervals, e.g., yearly, is unusual.
3. In the event of a large known exposure, either short term or prolonged, more frequent films may be indicated as determined medically.
4. Symptomatic individuals should be evaluated as determined medically.
5. A lateral film should be obtained only when indicated by findings on the PA film.
6. PA film on job change.

Equipment and Technique Standards

Detection of early radiographic change of pulmonary disease is dependent on good quality radiographs and comparable films from one examination to another. Use of high KV filming technique (120 to 150), short exposure, grids, proper screen-film combination, and carefully controlled processing techniques are essential to the production of the most consistent and good quality radiographs. Phototiming adds considerably to consistency from film to film. Details of proper equipment and technique standards have been published (33, 36).

Interpretation

(1) All films should be double read with at least the second reader being a certified *B* reader. The second reader should not be knowledgeable of any clinical factors or respiratory hazard exposure data, and films of nonexposed individuals should be submitted along with those exposed without knowledge of the reader.

(2) All films should be interpreted using the most recent ILO Classification System. A narrative report should accompany all positive films. In those cases in which significant discrepancy exists between the interpretation of the two readers, a reader recognized as an expert in radiographs of pneumoconiosis should serve as an arbitrator and give the final interpretation.

(3) When possible, comparison films should be submitted with the current film being evaluated.

Employee Education Program

Employee education functions are an integral part of an occupational respiratory disease prevention program. The medical persons charged to assist employers in protecting workers from acute or chronic respiratory health hazards should maintain the confidence and trust of employees exposed to these hazards in order that surveillance and hazard control be effective. The worker educational function should be delegated as a joint responsibility of production, personnel, safety, and medical staff persons. A physician is usually accountable for certifying the accuracy and appropriateness of the health related information, e.g., the explanation of potential respiratory hazard health effects, early symptoms or signs of injury or illness, recommended medical interventions if suspected overexposures occur, requirements for a medical intervention program including periodic tests on employees, and procedures for counseling employees on their respiratory health questions. Usually the educational program is carried out by a combination of distributed or posted written material or booklets plus informal small group counseling sessions.

As indicated above, physicians or nurses may carry out more personal and confidential counseling with individual employees regarding respiratory illnesses or medical test results. When these personal health problems affect the employee's fitness for job assignment or where reporting an occupational illness or condition is involved, the physician will be obligated to inform the employee of medical-legal issues and carry out the appropriate notifications of the employer and/or governmental agencies. Likewise, the physician may assist the environmental monitoring and control program by examining workers so as to determine whether the employee has a personal health condition that would require special job safeguards. Such personal health problems may involve communications with the employee's personal physician; hence, the occupational physician would enter into such communications only with the permission of the employee usually following a counseling session.

The responsibilities of employee health education for occupational respiratory disease protection, therefore, ranges from publication and dissemination of safe work practices or medical tests to be performed to very confidential counseling on personal medical matters.

General Purpose and Content

It is recommended that workers required to be in a medical surveillance program be afforded an opportunity to participate in an educational program directed to inform the workers of the nature of the agent(s), process(es), and area(s) where occupational respiratory disease hazards are known or suspected in the workplace. Also to be included in the educational program for employees assigned in designated hazard areas are each of the elements of a medical testing program; the primary purpose of this education is to obtain an informed consent for medical testing of all workers at risk. The worker should be advised as to the results of environmental measurements that form the basis for designating the workplace as a respiratory disease hazard area. The workers should also be informed of the recommended work practices to be used for mitigating the risk, the engineering controls, and any requirements for employee respiratory usage. Finally, employees should receive information on plans for continuing environmental surveys and medical monitoring of all respiratory disease hazard areas requiring surveillance. It is recommended that the education program be conducted on a periodic basis so as to assure the physician directing the medical surveillance program that there is a continued understanding of the environmental and medical measures being taken to protect the respiratory health of the worker.

Three Events that Trigger Education

Where a worker is to be hired for or transferred into a respiratory disease hazard area, the above education requirements should apply, including access to reports of environmental and medical data on groups of persons previously assigned to the work area and interpretations thereof. Also to be included in the available information prior to a placement decision would be any medical restrictions to be placed on the employee using the results of a preplacement examination; these results should be explained to the applicant or transferee. Each employee entering assignment in a respiratory disease hazard area should understand the early signs of an uncontrolled hazard, the basic purposes for monitoring, and the essentials for control.

Where a worker is assigned in a hazard area and an illness or injury occurs, temporary or permanent medical restrictions for the ill or injured worker shall be set by the attending physician. These restrictions shall include an assessment of the physical demands of the job and the environmental exposures in the hazard area. The rationale for these medical restrictions should be discussed with the worker at the time of return to duty.

At the time of transfer out of a respiratory hazard area or upon termination, the employee should be offered a medical examination. The employee should be advised as to the final medical findings obtained from this examination including those pertaining to the job hazards of that work area and those health effects that would not be reasonably detected until some future point in time because of the latent period for the medical hazard.

Evaluation

It is recommended that an independent evaluation of the effectiveness of the employee education program be carried out on a periodic basis, but not less frequently than every three years. This evaluation should include a review of the documentation of the education efforts undertaken and participation rates for employees in carrying out the objectives of informed consent of persons assigned to conduct the educational program.

This statement was prepared by the Task Group on Screening for Respiratory Disease in Occupational Settings. The Task Group members were as follows:

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AMERICAN LUNG ASSOCIATION
The Christmas Seal People®

March 17, 1987

The Honorable Howard Metzenbaum
Chairman, Subcommittee on Labor
Senate Committee on Labor and Human Resources
Washington, D.C. 20510

Dear Senator Metzenbaum:

Enclosed please find the answers to questions submitted to Dr. James A. Merchant as a result of the February 24 hearing on S. 79, The High Risk Occupational Disease Notification and Prevention Act.

If the American Lung Association can be of further assistance, please feel free to contact us.

Sincerely,

Fran Du Melle
Director

National Headquarters 1740 Broadway, New York, N.Y. 10019-4374 + James A. Swomley, Managing Director

QUESTIONS FOR DR. JAMES MERCHANT FROM SENATOR ORRIN G. HATCH

1. You mentioned that 1.2 million workers each year are potentially exposed to silica dust alone. Dr. Landrigan has already told us that the average cost for an initial medical screening exam is $224.00. That means that the initial cost to screen these workers would be in excess of $250 million. How frequently should these workers be seen in follow up and what will that cost? How many lives will be saved for this one-quarter of a billion dollar investment? And how many of those lives saved will be because the worker stopped smoking, something he or she could have done without a one-quarter billion dollar investment?

The question indicates the application of the proposed legislation has been misinterpreted in the example cited. I would estimate that less than 25% of those potentially at risk to silica exposure would be considered at "high risk". Of these, the vast majority are or should be under occupational surveillance by their employer. Those who are not or are retired would be a target for intervention. Right to know the risks of further exposure, the importance of regular medical surveillance including TB skin testing together with cigarette smoking cessation, in my view, would greatly assist reducing morbidity and mortality resulting from exposure to hazardous levels of silica. While the contribution of smoking cessation would be significant, so, in my view, would be further limitation of exposure and prevention of associated diseases such as Tuberculosis. In multifactorial diseases, all risk factors must be addressed to reduce occupational morbidity and mortality. You suggest that workers can stop smoking without the incentive of a program. It is very much more likely that workers will stop smoking when they understand that smoking interacts with their occupational exposure to greatly increase their risk to lung cancer and chronic obstructive lung disease and if there is a program designed for this purpose. It is only through prevention that the staggering occupational morbidity and mortality statistics cited in the American Lung Association statement, and their enormous costs, can be mitigated.

2. Based on your testimony and the testimony of others here today, it sounds like our number one occupational health hazard is tobacco smoke. Do you think the first substance a Risk Assessment Board should consider should be tobacco?

No. Clearly cigarette smoke is not an occupational exposure. Nevertheless, it is proper that smoking cessation be included in medical surveillance programs for high risk workers for the reasons just discussed.

3. I share your concerns about the make up of the Risk Assessment Board and the need for experts outside of the federal government. This seems in line with Senator Quayle's proposal. Would you like to comment on this?

My only concern about the Risk Assessment Board is that all of the scientists on the Board have occupational qualifications, be experienced in research, and respected members of the occupational health community. Because of the importance of biostatistics in risk assessment, I have recommended that a biostatistician from outside the government be added to the Board.

4. If you exclude cigarette smoking, how many lives can we save through medical follow up after the exposure has taken place? Would we be better off investing this money in preventing exposures as I have always advocated?

Certainly the best way to prevent occupationally caused disease is to prevent exposure. Unfortunately, because of inadequate legislation and inadequate funding and administration of current legislation, millions of workers have been adversely affected in the past and hundreds of thousands remain at high risk. Therefore, we need a very substantial increase in preventive measures in addition to specific programs for high risk workers, such as provided in S. 79.

5. Do you think its in the public's best interest to commit literally hundreds of millions of society's resources to notification, medical screening and medical follow up based solely on one animal study as S. 79 would allow, or should we require more realistic scientific evidence first?

This question is a distortion of the monies estimated for this program and the manner in which scientific data would be used. Animal studies are helpful particularly in assessing carcinogenicity and teratogenicity. One positive animal study will likely result in more animal studies and perhaps epidemiological studies of exposed human populations. One animal study will not trigger assessment of workers, in my opinion, and I would anticipate that only exposures with compelling evidence, usually based on several human studies, will be necessary to trigger notification and surveillance. Unfortunately, there are currently hundreds of thousands of workers at high risk for which such human data is now available.

6. Do you think individual notification is necessary in all cases or are there some areas where public service announcements might be appropriate?

I do not believe that individual notification is necessry in all cases. This judgement will need to be made by the Risk Assessment Board based on toxicity of the exposure, availability of the population at risk, and other considerations (i.e. those most at risk already covered by ongoing medical surveillance). Many useful models will be discussed at public hearings and made available to the Board. Further, some of the research monies provided for in S. 79 should be targeted to evaluation of notification and surveillance models.

Senator **Metzenbaum**. We will follow the rule of a five-minute period of questioning for each of the Senators, and if we need more than one round, we will do that as well.

We all know that medical surveillance has costs attached. But there are also health costs if workers contract a disease that could have been prevented or treated through early medical intervention.

I will ask each of you briefly to state whether, based on your experience, you would expect overall health care expenses to go up or down as a result of the medical surveillance contemplated under S. 79.

Dr. Landrigan.

Dr. **Landrigan**. Mr. Senator, our group at Mount Sinai Hospital, at the request of the New York State Legislature, has recently undertaken a year-long analysis of the problem of occupational disease in New York State. Based on workers' compensation data, New York State Health Department data, hospital discharge data, and a few lesser sources, we estimate that there are between 5,000 and 7,000 deaths which occur in New York State each year as a result of occupational disease, not injury, and that there are something like 35,000 new cases of occupational disease each year.

An economist in our group has attempted to calculate the costs which are associated with these occupational diseases in New York State alone, which contains only approximately 8 percent of the nation's workers. We estimate that the total costs in New York State per year are in the range of $600 million. And furthermore we state in our report, which will be released this week by the State Assembly, that this is no doubt a low figure because it does not take into account the added indirect costs that result from pain and suffering, family disruption, lost employment, lost future earnings.

In the same report we have put together for the State Assembly a proposal for a Statewide network——

Senator **Metzenbaum**. Dr. Landrigan, can I get you to zero in on the question?

Dr. **Landrigan**. Here it comes, Mr. Senator. We have put together a proposal for a Statewide network of occupational health clinics. Those have a price-tag of $6 million a year. So prevention is $6 million a year, the cost of disease is $600 million. We are talking about prevention adding up to one percent or less of disease costs.

The bottom line, then, is that intervention is cost-effective, it saves money, it is far more efficient and humane than treating disease after it has become clinically manifest.

Senator **Metzenbaum**. Thank you.

Dr. Seffrin.

Dr. **Seffrin**. I would concur. I would state that I remind you that one signal of the difficulty of the problem would be to look at the massive amount of Medicare costs that are consumed, something on the order of 40 percent of which are consumed by people during the last six months of their lives.

The American Cancer Society estimates that about 165,000 people, many of whom, of course, are workers, will die this year just because of late detection of disease. Cancer is a disease that distinguishes itself by not being highly treatable when detected late.

So the early detection of cancer as an example, we believe, would be highly cost-effective. We have published data that show, just to give an example of a worker who stops smoking before a tobacco and perhaps occupationally induced disease develops, it may cost on the order of $600 per person-year of lives saved. If we compare that to the treatment of disease such as bronchogenic carcinoma, the leading cause of cancer death among American male workers, we find that the cost is in the magnitude of $54,000 per patient-year of lives saved.

So over time we would expect this to be a highly cost-effective piece of legislation.

Senator METZENBAUM. Thank you very much.

Dr. Merchant, briefly?

Dr. MERCHANT. Yes. My specific experience with medical surveillance has to do with the cotton textile industry. Medical surveillance was an important part of the cotton dust standard when it was passed, and further studies of that standard have shown that medical surveillance played a very important role in reducing cases of byssinosis and chronic lung disease in that industry and that the cost of providing that standard was considerably less than had been originally estimated.

So this is, I think, one specific example that can be looked to.

Further, as I say in my testimony, I think the investment in this particular bill is really in part investment in better research and in improving the database by establishing exposure registries. By doing that, by performing further epidemiological studies, we are going to end up with better standards and be able to intervene and in that way, in the long run, I think the cost savings will be very substantial.

Senator METZENBAUM. Thank you very much.

I note that the original cosponsor of this bill last session as well as this time has joined us. Senator Stafford, we are happy to welcome you, and if you have an opening statement, I am sure my colleagues will yield to you for that purpose.

Senator STAFFORD. Well, thank you very much, Mr. Chairman. I am pleased to be an original cosponsor with you of this legislation.

I am reminded of that old New England saying that no matter how important you think you are, the size of your funeral will be determined by the weather. And in my case, the weather arranged a tree across our driveway so that I had to wait a while before I could get in to work.

But I am very glad to be here, and I am sorry I missed the opening statements and the statements of the distinguished witnesses at the table.

Senator METZENBAUM. Thank you very much, Senator Stafford. Senator Quayle.

Senator QUAYLE. Thank you, Mr. Chairman.

Dr. Seffrin, have you had an opportunity to review the outline of my proposal that deals with the process that I am trying to develop on how and when to notify, and the need for scientific expertise in the decisionmaking process and notification? Have you reviewed that?

Dr. SEFFRIN. I apologize, I have not. It was sent to me late last week. Unfortunately, I was out of the office, and then travelled here, so I have not seen that. I did see your statement of introduction, and certainly the intent of that is something that the American Cancer Society believes in, as I have stated.

I apologize for not having had a chance to look at it, but I can promise you I will.

Senator QUAYLE. In my opening statement today, I did outline some of the philosophical approaches and principles of developing ethical standards to deal with the notification process. Does the American Cancer Society agree with that basic philosophy and principles?

Dr. SEFFRIN. Yes. We believe, as I stated, that there needs to be a process whereby the worker who is exposed knows. And we know from the standpoint of not only the ethical standard of the need to know; we believe that it has educative value in terms of potential lifestyle changes which could, of course, intervene in the etiology of disease.

Senator QUAYLE. We have no problem with that. As a matter of fact, we support the idea that where you have this known information, go through a scientific process and where the risks are certain—then you determine how you are going to go about notification, whether it be individual notification, notification to the employer, notification to the doctor. And in our peer review process, we try to deal with the information and facts that are in these studies to help make this determination on the best information possible. I appreciate your general support for that idea.

Dr. Landrigan, the way I understand your testimony—and I was just trying to read it rather quickly here while listening to you—you basically believe that notification in all circumstances ought to be notification to the individual, when there is a study that shows a risk. Is that correct?

Dr. LANDRIGAN. I did not exactly say that, Mr. Senator. My bias goes in that direction.

Senator QUAYLE. Okay.

Dr. LANDRIGAN. I think that in most cases individual notification is best, because individual notification allows an opportunity for individual counseling, individual examination, conversation and education which is so much a part of medical practice.

There may be circumstances where it is simply impractical to individually notify workers. When I was at NIOSH, we discussed that possibility in some detail. Consider, for example, the case of a factory which closed down ten years ago, and the workers have scattered, and there are no very good records as to where they now are. Those circumstances most certainly exist.

In such cases, some form of notification through home town newspapers, through the mass media, or through some other approach, is almost inevitably going to be necessary.

Senator QUAYLE. Then, in some cases, you are saying that notification through mass media rather than individual notification would be an acceptable form of notification of certain risks?

Dr. LANDRIGAN. No, I am not quite saying that. I think I would like to make it quite clear that individual notification is the ideal. It is what is desirable. When it is not possible, maybe notification through the mass media will be necessary.

Senator Quayle. Let me just give you an example that we have right here in Washington, D.C., where it has been discovered that water flowing through lead pipes is causing some of the lead to flake off and be integrated into the water supply.

The District has basically responded to the situation by announcing it through the media as they work to replace these pipes. Obviously, they could go out and find all the individuals who receive water through these pipes and go through the process of individual notification.

Now, under that real situation, how would you go about it, and how do you think S. 79 would provide for that? Would you recommend individual notification, or do you think, as the District has done here, notification through the mass media is adequate? This is a real situation. This is not a hypothetical.

Dr. Landrigan. You touch a subject close to my heart, because I was trained in pediatrics, and I have done a lot of work with lead poisoning. In fact there is another mechanism in place in the case of lead poisoning, and that is the Lead Paint Poisoning Prevention Act of 1971, which provides funds for the screening of children in high-risk areas for lead. Unfortunately, I understand that that program has mostly been de-funded in recent years, but it provides a legal mechanism for sending health departments door-to-door to take blood tests on children, to screen them for lead levels, to screen them for erythrocyte protoporphyrin levels. And, in the case of highly mobile populations among inner-city children where there is a high prevalence of exposure to lead from many sources—water is only one of those—mass notification is only a partial solution, and individual notification with door-to-door visits by Public Health nurses is clearly far more effective.

Senator Quayle. So, under this situation, you would recommend individual notification rather than what the District has done; is that correct?

Dr. Landrigan. Oh, yes. In New York City, where the lead paint poisoning prevention moneys have diminished, we have seen an increase in lead poisoning. When there was door-to-door individual home visits, the incidence of childhood lead poisoning was way down.

Senator Quayle. Okay.

Thank you, Mr. Chairman.

Senator Metzenbaum. I would note that Senator Harkin, a member of this Committee, has joined us. Senator Harkin, do you have questions?

Senator Harkin. Thank you, Mr. Chairman. I really do not have any questions, other than just to welcome Dr. Merchant, who is from my home State of Iowa, from the University of Iowa, and to thank him for his basic support of the thrust of S. 79.

Mr. Chairman, I have not read all of the testimony yet; I am sorry that I was at another hearing. I am concerned about the high-risk occupations in the high-tech industries, especially in computer chip manufacturing where highly-toxic chemicals are used. Has that been covered? If it has, that is fine; if it has not, I just wonder if any of you are knowledgeable in that area in terms of the fumes that some of these workers breathe when they make a lot of these computer chips, and whether that is an area that we ought to be looking at.

I know a lot of talk is given to silica dust and asbestos and agricultural material, but not too much attention has been focused on the new high-tech industries and some of the toxic chemicals that are used there.

I would just address it to the panel.

Senator **Metzenbaum**. Do any one of you wish to respond?

Dr. **Landrigan**. There are certainly many toxic chemicals in the high-tech industry. Arsine gas, which is a hydride of arsenic, is an acute hemolytic toxin that is used to dope crystals; silica is present in the crystals themselves; and some of the gases of boron which are used to dope the crystals have toxic effects. There has been concern about the toxic effects of solvent in the industry.

I also think it is fair to say that many of these toxic effects have not yet been fully defined, and there is a fair need for further research into this expanding area of technology.

Senator **Harkin**. Is there research being done in this area?

Dr. **Landrigan**. When I was at the National Institute for Occupational Safety and Health, some research in the area was being done. With the enormous cutbacks in funding for that agency that have taken place, I am of the strong opinion that the amount of research is not adequate.

Senator **Harkin**. There have been numerous stories written about women who work in these positions. They are not highly-paid positions, but they are positions that require exposure to these chemicals. There are indications, that there may be some very long-term effects, particularly on women of childbearing years, and the problems that they have encountered after exposure to these toxic chemicals and these fumes over a period of time.

Again, I am just asking if more research needs to be done in this area, or if we have cut back on that area; do you know whether we have cut back in this area?

Dr. **Landrigan**. Well, there has certainly been recent publicity about the dangers—or, the purported dangers—to working women of being in those industries, and I think some of that concern is well-placed.

It is also, of course, wise to bear in mind that men as well as women carry their reproductive organs to work with them, and therefore, workplaces have to be safe enough to protect workers of both sexes.

Senator **Harkin**. I recognize that.

[Laughter.]

Senator **Harkin**. Thank you, Mr. Chairman.

Senator **Metzenbaum**. Senator Hatch.

Senator **Hatch**. Well, thank you, Mr. Chairman.

Dr. Landrigan, I would like you to provide for the Committee a list of known occupational diseases if you would; just give it to us as best you can—I do not mean right now. I mean at your leisure.

[Information supplied for the record follows:]

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Philip J. Landrigan, M.D., M.Sc.
Director, Division of Environmental
and Occupational Medicine
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(212) 650-6173

February 26, 1987

Mr. James J. Brudney
Majority Counsel
Senate Labor Subcommittee
United States Senate
608 Hart Senate Office Building
Washington, D.C. 20510

Dear Jim:

Enclosed please find a copy of the monograph entitled "Occupational Disease in New York State" which our group at Mount Sinai has just prepared for the New York State Assembly, and which I mentioned during my testimony before Senator Metzenbaum on February 24.

All best regards.

Sincerely,

Philip J. Landrigan, M.D.
Professor

PJL:jlr
Enc.

(Editor's Note: Due to printing limitations, and in the interest of economy, the monograph referred to above was retained in the files of the committee, where it may be researched upon request.)

Senator HATCH. You said in your statement that the criteria for notification adopted in S. 79 were generally reasonable. As I understand the scientific criteria, one animal study could be enough to require notification of a large human population; or, one study which exposed a small number of subjects to a large dose might be enough to require notification of individuals who were only exposed to low doses; or, a study based on long-term exposure could require notification of workers who only have a short exposure time.

Now, I am not a scientist, but I have to admit, that does not look very scientifically sound to me. Would you consider those examples I just listed as acceptable scientific criteria for notification?

Dr. LANDRIGAN. Well, the point is well-taken. Obviously, the trigger for notification has to be carefully considered.

Senator HATCH. You can see why I do not think this has been carefully considered.

Dr. LANDRIGAN. The operative word in your hypotheticals, I think, though, is the word "might". There have been developed over the past several decades some very sound procedures for evaluating the results of both animal studies and human studies in terms of occupational exposures. These procedures have been best refined by the National Cancer Institute——

Senator HATCH. But if we go with this bill, it is going to allow any type of bizarre approach.

Dr. LANDRIGAN. Well, these procedures that have been developed over the past couple of decades provide a nice, sound, ethical, scientific framework for evaluating studies. I have served on several expert panels that have undertaken these sorts of reviews, and a single poorly-conducted study does not upset the apple cart. When a single study that is not well-conducted is reviewed, it is discarded.

Senator HATCH. I understand that. Let me ask you this. Would you support an amendment that would exclude those types of distorted approaches?

Dr. LANDRIGAN. Well, I would argue with you that the mechanism is in place in the bill now in the form of the Expert Board for undertaking the sort of expert review which would sift out the bad studies and make frivolous notification most unlikely.

Senator HATCH. Let me just say this. You stated that notification could be accomplished with relative efficiency with regard to individual workers. In your testimony, you only talked about how easy it would be for the Federal government to notify. But you know, one of the problems that concerns me is how easy is it going to be for businesses to notify individuals. They would have to track down, under this bill, every worker who has worked with them for the past 30 years, who might possibly have been exposed. So these are problems.

Let me just ask you to comment on that in writing, if you will, but because my time is short, let me just bring up one other thing—and I bring it up to all three of you.

Dr. Landrigan testified, of course, that it would cost $224 per screening visit—that would be the average cost. Dr. Merchant has testified that in the case of silicosis, there would be 1.2 million workers per year exposed to silicosis.

Of course, if you just take the cost of medical screening at $224, times 1.2 million, that comes to $268 million per year for just one exposure for one disease. And I assume everyone here in this room knows there will be many, many diseases.

I think you would also have to agree that, except for those who stop smoking, I do not think anybody knows of any benefit from this investment in terms of longer lives, because the smoking is the major problem.

So you have two alternatives. One is to reduce exposure, or two, have a smoking cessation program.

Senator METZENBAUM. Senator Hatch, I do not mean to interrupt you, but I think that you have misinterpreted something Dr. Landrigan said. I think you totalled up his list of expenditures.

Is that an appropriate thing to do, Dr. Landrigan, or would you have to use only some of those expenses?

Dr. LANDRIGAN. Well, no. That is what it adds up to, but not every test would be applied in every case.

Senator HATCH. I agree. But you said that would be your estimate of the average cost.

Dr. LANDRIGAN. It is not far off; I would agree.

Senator HATCH. That is the point. So if you start talking about one exposure, $268 million. The major way to get around it would be to get people to stop smoking.

Well, let me just ask Dr. Seffrin this. Should those who refuse to quit smoking expect the government or their employers to provide all of the care and treatment and safety mechanisms for them at the cost of $268 million just for one exposure for one occupational disease a year? That is a bizarre example, but that is using Dr. Merchant's and Dr. Landrigan's figures, and you have got to talk about many, many other exposures besides that.

Let us say it is $50 million. It is still going to be a tremendously inordinate cost in some of these areas where people just will not quit smoking. And that is an awful lot of what they have to do.

Well, my time is up, but let me just say this. I have spent a lot of my time in the ten years that I have been in Congress working on health promotion and disease prevention. And it seems to me what we are saying here is let us just saddle industry for all of the costs of the people who smoke in our society, notification being one of the major costs and screening being another cost, and let us just do this because in our hearts we feel we have just got to do everything we can to make sure that everybody is taken care of by the Federal government.

These are some of the questions that bother me about this type of a bill—even though I am as concerned as I think all three of you are about having safe workplaces and good health approaches.

Senator METZENBAUM. The time is rapidly running out on us. The Chair had originally indicated that we might have several rounds of questions. The Chair himself has some questions that he would like to ask, but if my colleagues do not object, I would like to suggest that I and the others who still have questions submit our questions in writing to you and hopefully, you will respond promptly to those questions.

Senator QUAYLE. I had two or three questions, but I wonder if I could just ask one question.

Senator METZENBAUM. Go ahead.

Senator QUAYLE. S. 79, Dr. Landrigan, one of the provisions problem is that: no school of medicine may receive Federal financial assistance in any academic year, after the enactment of this Act, unless the school of medicine offers a course of study on occupational disease consisting of a minimum of 20 actual hours of didactic and practical instruction.

Do you agree with that? Should we cut off all Federal funds if they do not do precisely as we say?

Dr. LANDRIGAN. A recent study indicates that the average American medical student receives four hours of training in occupational health in his or her four years as a medical student. That is probably inadequate. Occupational histories are only recorded on something like 10 percent of hospital charts in this country.

I think it is clear that more training in occupational health is needed. Most doctors simply do not know how to take an occupational history from their patients.

Senator QUAYLE. Do you support the provision in this bill that medical schools must offer 20 hours; otherwise, they are going to lose all Federal financial assistance?

Dr. LANDRIGAN. I certainly think there should be more training in occupational medicine in schools.

Senator QUAYLE. Well, I understand that. The question is, do you support this provision of this bill—to cut off all Federal funds to medical schools that do not have the 20 hours—or is that going a bit far?

Dr. LANDRIGAN. That might be going a bit far.

Senator QUAYLE. Dr. Seffrin? Think of I.U. School of Medicine when you answer this.

Dr. SEFFRIN. I was just about to say, Senator, I am glad that I am not the chair of a department in our School of Medicine. I would not want to comment, not being a physician, on what the medical school curriculum should be like. I do believe that the intent is good, and the American Cancer Society would support the intent. We would leave the specific requirements and language to you to work out, whether that is reasonable, in other words, for 20 hours.

Senator QUAYLE. In other words, you would stay away from actually prescribing number of hours in the curriculum.

Dr. SEFFRIN. That might be wise.

Senator QUAYLE. Would that be your position—the intent to encourage more study in this area is fine, but getting into specific number of hours and talking about denying Federal financial assistance in any academic year. I mean, that is rather severe.

Dr. SEFFRIN. That is severe. I agree that that is severe.

Senator QUAYLE. So you think this might be going a bit too far?

Dr. SEFFRIN. I think that there have to be strong incentives, if not mandates, in the bill to improve the surveillance, detection and early diagnosis of disease.

Senator QUAYLE. How about cutting off Federal financial assistance? Do you want to do that if they do not live up to 20 hours?

Senator METZENBAUM. I want to say to my colleague that we are working with the medical schools on that subject, and I hope that when we get that problem resolved, he will then come on as a cosponsor, because we will get it resolved. [Laughter.]

Senator QUAYLE. That is one of the minor concerns that the Senator from Indiana has. But I am glad that the spirit of accommodation and recognition that there are going to have to be some changes, is apparent.

Senator METZENBAUM. I said that in my opening statement, and there is no question about it. We are prepared to work with the various groups who are involved. We want to bring about a bill that can get as great a consensus of support as possible.

Gentlemen, thank you very much for joining us this morning.

Senator QUAYLE. Mr. Chairman, I have a statement from Senator Humphrey, an opening statement he would like inserted in the record at the appropriate place.

Senator METZENBAUM. Without objection, it will be inserted in the record.

Thank you very much, gentlemen.

Our next panel includes Dr. Robert Windom, Assistant Secretary, Department of Health and Human Services, and Dr. James Melius, Director of the Division of Surveillance, Hazard Evaluation and Field Studies at the National Institute of Occupational Safety and Health.

Dr. Windom, I think you heard that we are asking our witnesses to confine their remarks to five minutes. We will be happy to put your entire statement in the record.

Dr. WINDOM. Fine. Thank you, Mr. Chairman.

Senator METZENBAUM. Thank you. We are happy to have you with us. And I think there is an additional doctor here with you, Dr. Millar. We are happy to welcome you as well, sir.

Would you be good enough to tell us who Dr. Millar is?

Dr. WINDOM. Yes. Dr. Millar, on my far right, Mr. Chairman, is the Director of NIOSH, and Dr. Jim Melius, to my direct right, is the Director of the Division of Surveillance and Hazard Evaluations, and Field Studies, NIOSH, at the CDC.

Senator METZENBAUM. Thank you.

STATEMENT OF DR. ROBERT WINDOM, ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY DR. JAMES MELIUS, DIRECTOR, DIVISION OF SURVEILLANCE, HAZARD EVALUATIONS AND FIELD STUDIES, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH; AND DR. J. DONALD MILLAR, DIRECTOR, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Dr. WINDOM. Thank you, Mr. Chairman.

I am Dr. Robert Windom, the Assistant Secretary for Health. I am pleased to have the opportunity to represent the Administration's views on S. 79 today.

As you know, in the previous Congress, representatives of this Department and the Departments of Justice and Labor presented views strongly opposing similar legislation. Although we support notification of adverse findings when appropriate to subjects of Federally-conducted occupational health research, there continue to be major problems with S. 79 which illustrate the difficulty of dealing with the complex issue of notifying workers about potential health risks.

We therefore must continue to oppose this legislation.

We do not believe additional legislation is needed for NIOSH's worker notification efforts to continue, since they are already an integral part of much of their research. NIOSH notifies workers of the results of all field research and shares findings with employers, relevant unions or employee representatives, the Department of Labor and appropriate State agencies.

In addition, for all studies initiated by a request for assistance from an employer or employee representative through the health hazard evaluation program, reports are sent to the requester and posted at the worksite for 30 days or sent directly to the individual employees.

Where NIOSH has examined individuals in conducting the studies—for example, in cross-sectional medical studies—it notifies those involved of their individual results. Aggregate findings are also distributed through the scientific literature and through special publications available to the public and media.

Of the approximately 3,800 field studies that NIOSH has conducted, it is the approximately 90 retrospective cohort mortality studies, about which most of the individual worker notification concern has been raised.

In retrospective cohort mortality studies, personnel records for selected plants are received, and it is determined as a group if the cohort experienced more than the expected number of deaths from specific diseases.

Even though aggregate study results have been made available in these NIOSH studies, some have expressed concern that surviving workers should be informed individually of study results so they can seek medical consultation.

NIOSH has been addressing these concerns about the retrospective cohort mortality studies. They conducted two pilot projects starting in 1977 and 1979. To summarize, the health consequences and societal concerns about notification made clear the importance of counseling, accurate information about risk, medical screening and treatment, and the need to involve a larger cross-section of the community than just the affected employees.

Three factors were found to be critical: (1) special care has to be taken to avoid what we call "false" notification, for worker notification must be based on scientifically sound judgment and information; (2) accurate information should be available to workers, their families and community physicians, and other involved parties, and (3) communities, the medical system, and the State and local agencies need to be prepared to respond to needs which may include counseling, medical screening and treatment.

Based on the results of the pilot projects, NIOSH then developed a "decision logic", a system for determining which studies, past and future, should be included in individual worker notification effort.

To date, NIOSH has applied the decision logic to one candidate study, as a pilot effort. One of these documents will be developed for each study that is a candidate for notification.

In fiscal year 1987, it is planning to select five studies which will contain disease risks amenable to intervention for development of Notification Assessment Documents.

As we have noted, the Administration strongly believes that additional legislation is not needed. While we share the Committee's concern about protecting employees from hazards in the workplace, we do not feel that a new Federal program is necessary for this purpose. The substantial, ongoing efforts of NIOSH, which I have cited before, and the Department of Labor already provide a mechanism for effective worker notification.

We also note that the scope of the worker notification program envisioned by S. 79 may have an adverse influence on State workers' compensation programs because the fact that claimants have been notified by the Federal government that they are "at risk" may be incorrectly interpreted to mean that disease in the claimant was caused by employment.

We do not support the establishment of additional Occupational and Environmental Health Centers. The training provisions of these new centers would clearly duplicate the existing Educational Resource Centers already funded by the Department.

We strongly oppose the provisions mandating specific curricula requirements at medical schools because we feel it represents an unwarranted Federal intrusion into decisions that are properly those of individual medical schools themselves.

Senator METZENBAUM. Can you wind up, Dr. Windom?

Dr. WINDOM. In conclusion, Mr. Chairman, we believe that S. 79 is unnecessary because we can build on current OSHA and NIOSH programs. This would provide an adequate focus and would not call for a new Federal program.

However, despite our strong opposition to this legislation, we hope it does not preclude a continuing dialogue with your Committee during the deliberations on this, and we would like to have the opportunity to look more closely at Senator Quayle's approach as this becomes more defined.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Windom follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

STATEMENT OF

ROBERT E. WINDOM, M.D.

ASSISTANT SECRETARY FOR HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON LABOR

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

February 24, 1987

Mr. Chairman and Members of the Subcommittee:

I am Dr. Robert E. Windom, Assistant Secretary for Health in the Department of Health and Human Services. Thank you for inviting me to present the Administration's views on S. 79, the High Risk Occupational Disease Notification and Prevention Act of 1987. With me today are Dr. J. Donald Millar, Director of the National Institute for Occupational Safety and Health (NIOSH) and Dr. James Melius, Director of NIOSH's Division of Surveillance, Hazard Evaluations and Field Studies of the Centers for Disease Control.

Mr. Chairman, as you know, in the previous Congress, representatives of this Department and the Departments of Justice and Labor presented views strongly opposing similar legislation. Although we support notification of adverse findings when appropriate to subjects of Federally-conducted occupational health research, there continue to be major problems with S. 79 which illustrate the difficulty of dealing with the complex issue of notifying workers about potential health risks. We therefore must continue to oppose this legislation.

Current Efforts of NIOSH

We do not believe additional legislation is needed for NIOSH's worker notification efforts to continue, since they are already an integral part of much of their research. NIOSH notifies workers of the results of all fieldresearch, and shares findings with employers, relevant unions or employee representatives, the Department of Labor and appropriate State agencies. In addition, for all studies initiated by a request for assistance from an employer or employee representative through the health hazard evaluation (HHE) program, reports are sent to the requester and posted at the worksite for 30 days or sent directly to the affected employees. Where NIOSH has examined individuals in conducting the studies—for example, in cross sectional medical studies—it notifies those involved of their individual results. Aggregate findings are also distributed through the scientific literature and through special publications available to the public and media.

Of the approximately 3800 field studies that NIOSH has conducted, it is the approximately 90 retrospective cohort mortality studies, about which most of the individual worker notification concern has been raised. In retrospective cohort mortality studies, personnel records for selected plants are received and it is determined if, as a group, the cohort experienced more than the expected number of deaths from specific diseases. Even though aggregate study results have been made available in these NIOSH studies, some have expressed concern that surviving workers should be informed individually of study results so they can seek medical consultation and other assistance if they desire to do so

NIOSH has been addressing these concerns about the retrospective cohort mortality studies, It conducted two pilot projects starting in 1977 and 1979 to notify workers individually These projects were discussed in detail in our testimony last year. To summarize, the health consequences and societal concerns about notification made clear the importance of counseling, accurate information about risk, medical screening and treatment, and the need to involve a larger cross-section of the community than just the affected employees. Three factors were found to be critical in any notification program: (1) special care has to be taken to avoid what we call "false" notifications (worker notification must be based on scientifically sound judgment and information); (2) accurate information should be available to workers, their families, and community physicians and other involved parties; and (3) communities, the medical system, and State and local agencies need to be prepared to respond to needs which may include counseling, medical screening and treatment.

Based on the results of the pilot projects, NIOSH then developed a "decision logic," a system for determining which studies (past or future) should be included in an individual worker notification effort. NIOSH also developed a list of candidate studies (where overall dissemination of results already has taken place) to which the decision logic will be applied.

To date, NIOSH has applied the decision logic to one candidate study, as a pilot effort, and a draft of a model "Notification Assessment Document," (which reviews the findings from applying the decision logic to a study) has been developed. One of these documents will be developed for each study that is a candidate for notification.

As mentioned earlier, there are approximately 90 candidate studies. NIOSH has categorized them according to whether or not they contain disease risks amenable to intervention. In fiscal year 1987, it is planning to select five studies containing disease risks amendable to intervention for development of Notification Assessment Documents. NIOSH will then proceed with notification efforts for these five studies as appropriate.

NIOSH is also involved in other worker notification efforts separate from those just described. One of these includes assisting a company in notifying its employees of the results of a NIOSH study which showed an increased risk of death from certain cancers. With regard to future NIOSH studies, the agency is also developing a policy requiring that plans for epidemiological studies address the need for individual worker notification. NIOSH plans to apply the decision logic, "Guidelines for Notification of Individual Workers," in the development of protocols for all epidemiologic studies.

Comments on S. 79

As I have noted, the Administration strongly believes that additional legislation is not needed. While we share the Committee's concern about protecting employees from hazards in the workplace, we do not feel that a new, Federal program is necessary for this purpose. The substantial, on-going efforts of NIOSH, which I cited above, and the Department of Labor already provide a mechanism for effective worker notification.

A major flaw in the legislation is that the legal issues raised by the Administration in the 99th Congress in testimony and reports by the Department of Justice have not been resolved. The bill would expose the United States and its employees to potentially enormous liability. This could result in substantial litigation, in many cases without merit, imposing enormous costs on consumers, workers, and the Federal government. In addition, this could add thousands of new lawsuits to the already-burgeoning tort dockets of the Federal courts.

We also note that the scope of the worker notification program envisioned by S. 79 may have an adverse influence on State workers' compensation programs, because the fact that claimants have been notified by the Federal government that they are "at risk" may be incorrectly interpreted to mean that disease in the claimant was caused by employment.

Other more specific concerns we have with S. 79:

- We do not support the establishment of additional Occupational and Environmental Health Centers. The training provisions of these new centers would clearly duplicate the existing Educational Resource Centers (ERCs) already funded by this Department. We have adequate authority for research on hazardous substances through these ERCs and the National Institute of Environmental Health Sciences (NIEHS) and National Cancer Institute (NCI) centers. However, these centers are generally not equipped to conduct surveillance and to provide medical treatment and family services to employees exposed to occupational hazards; we believe it is unnecessary and inappropriate to establish such an open-ended services requirement.

o We strongly oppose the provisions mandating specific curricula requirements as a general condition for Federal funding to medical schools. While we recognize the importance of including instruction on occupational disease in the medical school curriculum, such a provision is both unworkable and impractical, and represents an unwarranted Federal intrusion into decisions that are properly those of individual medical schools.

o S. 79 does not provide the Secretary of HHS with the power ultimately to determine which individuals should be notified, but places it with the Risk Assessment Board. We oppose the creation of an independent authority below the level of the Secretary. There may also be questions about the constitutionality of such an authority.

o The mandate to notify at least 100,000 employees each year has no scientific or medical basis, and gives the appearance of capriciousness.

We commend both Chairman Metzenbaum and Senator Quayle for their respective efforts to address the concerns the Administration has raised about this legislation.

While clearly underscoring that we do not agree with the premise that there is a need for this legislation, let us note that—from a public health perspective—S. 79 does contain some improvements over past bills.

We feel that the scope of the legislation has been better defined; in some respects the central scientific issue of targeting groups for notification has been improved, thus limiting the requirement in earlier bills to extrapolate to whole classes or categories of workers; and the use of public service announcements is a reasonable alternative to time-consuming efforts to attempt notification for hard-to-reach individuals.

SUMMARY

In conclusion, Mr. Chairman, we believe S. 79 is unnecessary because we can build on current OSHA and NIOSH programs which already are evaluating and communicating the nature of workplace hazards to employees. This would provide the appropriate focus, would not call for a new, Federal program, and would obviate the legal concerns I cited earlier.

I have discussed NIOSH's on-going efforts. The Department of Labor (DOL) is in the process of expanding its Hazard Communications Standard to insure that workers receive notification about chemical hazards to which they are exposed on the job, and training in avoidance of those hazards. In addition, I understand DOL is exploring the feasibility of a generic medical surveillance standard which could be applicable to all of OSHA's standards.

Despite our strong opposition to this legislation, we hope this does not preclude a continuing dialogue with your Committee during the deliberations on this issue. Senator Quayle has recently developed a different appropach to addressing notification of individuals who may be at high risk of disease. We would like to have an opportunity to look closely at his approach, as well as discuss the Administration's concerns in more depth.

This concludes my testimony. My colleagues and I would be happy to answer any questions at this time.

Senator Metzenbaum. Dr. Melius, last year, you criticized our predecessor bill, S. 2050, as scientifically inadequate. Do you believe that S. 79 is a medically sound and scientifically workable approach for notifying specific groups at risk of occupational disease?

Dr. Melius. Yes, I do.

Senator Metzenbaum. Would you tell us what changes in S. 79 led you to this conclusion, in summary form?

Dr. Melius. Yes. I think there have been two major changes in the bill. One is the revised definition of what groups would be at significant risk and should be notified. And I believe that the new definition including "statistically significant risk" in a "scientifically sound study", and with the priority given to populations that would medically benefit, provides a very sound basis for determining who should be notified.

The second major change in the legislation was the provision allowing group notification to be used when individual notification is not feasible. In my testimony on the previous bill, one of our concerns was the difficulty in reaching certain populations and the high costs associated with those workers in small businesses, businesses that are no longer in existence, or where there are poor records. I believe that the flexibility given by the new approach makes a significant improvement in allowing this kind of notification to be done very feasibly and very reasonably.

Senator Metzenbaum. Thank you.

Last year, you testified that the costs of identifying, locating and notifying former employees, which you called the most serious costs involved with the bill, would be $40 to $55 per person. Have you looked into the overall costs that HHS would have to bear in administering S. 79—I refer here to the personnel and related costs of running the Risk Assessment Board, staffing the notification process and telephone hotline, certifying employers who wish to do their own notification, writing reports, promulgating regulations, and conducting the necessary research, training, monitoring and enforcement activities?

Dr. Melius. Yes. At your request, for this hearing, we have prepared estimates on costs and personnel involved in that. I do not necessarily want to go into a lot of detail on this, but looking at the revisions in the bill, and looking at the target figures for notification of 100,000 to 300,000 workers, we feel that all provisions of the bill can be implemented within the estimated authorization for this bill.

We estimate that with 10 centers being funded and 100,000 workers notified, it would cost approximately $20 million per year. That would include funding and staffing all the other provisions of the bill—the Notification Board, the recordkeeping requirements, and so forth.

For 300,000 workers and 10 centers, we would estimate the total cost to be on the order of $26.5 million, which is slightly over the $25 million, though no doubt, with adjustments and depending upon the population selected, even the 300,000 figure could be reasonably met.

Senator Metzenbaum. So that the $25 million figure that we have in the bill, in your opinion, is a reasonable one?

Dr. **Melius**. Yes—combined with the targeting—we think the provision in this bill allowing the prioritization of populations to be notified is very important. The effort is directed at those that would most benefit from this type of notification.

Senator **Metzenbaum**. Would you be good enough to furnish the Committee with a copy of this year's overall cost analysis, as well as last year's notification cost analysis, which frankly never found its way into the record?

Dr. **Melius**. Yes, we would be glad to provide that.

[Information supplied for the record follows:]

SECTION BY SECTION ANALYSIS OF S.79
DIRECT ANNUAL COSTS AND PERSONNEL NEEDS FOR DHHS

SEC. 4 RISK ASSESSMENT BOARD

It is estimated that the costs for operating the Risk Assessment Board would approximate $700,000 per year. This includes personnel costs (members and staff), support costs, and costs for collecting needed information from existing research and data sources. The FTE required for the Risk Assessment Board would be 12.

SEC. 5 EMPLOYEE NOTIFICATION AND COUNSELING

1. It is estimated that 10 FTE would be used for this activity, and there would be overlap with the responsibilities of the staff time committed to the Risk Assessment Board. The estimate for notifying workers is $33 per worker notified.* (It should be noted that the personnel costs for the 10 FTEs are included in the $33 figure.) Therefore, the costs for notifying 100,000 - 300,000 workers per year would be 3.3 - 9.9 million dollars.

2. The cost for operating the "hotline" would approximate $55,000 annually, including one additional FTE.

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* See attached memorandum dated January 23, 1986.

3. It is approximated that 3 additional FTEs will be necessary for dissemination of medical and health promotion material as a result of risk determinations. The total cost of this effort, including personnel costs, would approximate $250,000 annually.

SEC. 6 MEANS OF EMPLOYEE NOTIFICATION

It is approximated that 2 FTEs would be needed for certifying private employers or state or local governments. The total cost of this effort, including personnel costs, would approximate $200,000 annually.

SEC. 7 OCCUPATIONAL AND ENVIRONMENTAL HEALTH CENTERS

1. Each of the 10 centers to be established under the bill would need 4 full-time professionals for notification-related activities. These would include a physician, a clinic referral coordinator, a special services professional, and a director of medical training activities. It is estimated that these costs for these personnel would be $250,000 per center per year. In addition, it is estimated that the costs for the training prescribed in the bill would be $250,000 per year per center. This would cover five training courses per year. It is estimated the costs for technical assistance/research prescribed in the bill would be $250,000 per year per center. Including 50 percent overhead costs, it is estimated that total costs for the initial 10 centers would be approximately $9 million per year. To establish an other 40 centers (one in each state), it is estimated that more modest budgets would be needed

to support notification efforts. Assuming support for base staff and training activities of $250,000 per year, these other centers are estimated to cost $10 million per year. This would include funding for a clinical coordinator, a training professional, and a part-time physician.

2. It is approximated that 3 "inhouse" FTEs will be necessary to monitor and support this program. The total inhouse cost of this effort, including personnel costs, would be $250,000 annually.

SEC. 8 RESEARCH, TRAINING AND EDUCATION

1. The new research that would be required by this bill, in addition to that already being conducted under the Occupational Safety and Health Act and Mine Safety and Health Act, would approximate 5 million dollars annually. (It is assumed that these funds are separate from what would be provided to the health centers under Section 7.) The 5 million dollars would include the personnel costs for approximately 25 FTEs.

2. It is estimated that 2 FTEs would be needed to monitor the "Courses of Study on Occupational Disease". The total cost of this effort, including personnel costs, would approximate $200,000 annually.

SEC. 10 ENFORCEMENT AUTHORITY

It is estimated that 4 FTEs would be needed for the recordkeeping and enforcement aspects of the bill. The total cost, including personnel costs, would be $300,000 annually.

SEC. 11 REPORTS TO CONGRESS

It is estimated that one FTE would be needed for maintaining information and preparing the Annual Report to Congress. The total cost of this effort, including personnel costs, would be $100,000 annually.

SEC. 12 SUBJECTS OF FEDERAL AGENCY STUDIES

It is estimated that 20,000 workers per year would be notified pursuant to this section of the bill. This effort would require 4 FTEs. The estimated cost is $26 per worker notified.* Thus, the total cost annually would be approximately $500,000. (It should be noted that the personnel costs for the 4 FTEs are included in the $26 figure.)

SEC. 13 REGULATIONS

Costs for promulgating regulations are included in the estimates listed above.

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* See attached memorandum dated February 3, 1987.

SUMMARY OF ESTIMATED ANNUAL DIRECT DHHS COSTS AND PERSONNEL NEEDS FOR S.79

SECTIONS OF BILL

	4	5				6	7		8		10	11	12
		NOTIF.											
		100,000	300,000	HOTLINE	DISS.		10 CTRS	50 CTRS	RES.	COURSES.			
FTEs	12	10	10	1	3	2	3	3	25	2	4	1	4
TOTAL FUNDS ($000)	700	3,300*	9,900*	55	250	200	9,250	19,250	5,000	200	300	100	500**

TOTAL FTEs - 67

TOTAL COSTS

(a) 100,000 workers notified & 10 centers - $19,855,000

(b) 100,000 workers notified & 50 centers - $29,855,000

(c) 300,000 workers notified & 10 centers - $26,455,000

(d) 300,000 workers notified & 50 centers - $36,455,000

* Costs would increase/decrease by $33,000 for every 1,000 workers notified/not notified.

** Costs would increase/decrease by $26,000 for every 1,000 workers notified/not notified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date February 3, 1987

From Chief, Screening & Notification Activity, IWSB

Subject Cost of Worker Notification When Incorporated into Study Plan

To James M. Melius
Director, DSHEFS
Through: Chief, IWSB 2/4/87

At your request I have calculated the costs of individual worker notification when it is incorporated in the study plan rather than done after the fact. The latter was estimated to cost approximately $33 per subject (see attached memo).

For the incorporated approach the cost would be $26 due to the fact that cohort location, file update and personnel costs would be reduced. For a 10,000 person cohort the itemized costs would be as follows:

1.	Cohort location @ $0.19/subject	$ 1,900
	Special follow-up; 10% @ $2.00/subject	$ 2,000
	Reduced by 10%	
2.	File update, coding, letter preparation Hotline	$ 22,575
	Reduced by 25%	
3.	Material @ $2.50/subject	$ 25,000
	Same	
4.	Personnel - Year 1, 4 people @ $35,000	$140,000
	Year 2, 4 people for 0.33 year	$ 46,200
	Reduced by one person since project officers would handle the matter in tripartite review and other meetings	
5.	Travel	
	Totaled for 10,000 subjects	$ 22,500
	Reduced by 25% since one less trip would be needed due to discussion of the matter in tripartite review.	$260,175

Paul A Schulte

Paul A. Schulte, Ph.D.

Attachment

June 20 1986

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
ESTIMATED COSTS OF NOTIFICATION BILL (S. 2050)

I. SET UP RISK ASSESSMENT BOARD

This would require hiring staff for the board (5 FTE) and obtaining information for initial reviews, etc. This would cost approximately $500,000 each year.

II. SET UP OCCUPATIONAL AND ENVIRONMENTAL HEALTH CENTERS

Each of the initial ten centers would require at least four full time professionals for notification related activities. These would include a physician, a clinic referral coordinator, a special services professional, and a director of medical training activities. (Estimated cost $250,000) per year.

In addition, they would need funding for the training efforts ($100,000 for five courses per year) and for research efforts related to these activities ($250,000 for a modest effort in this area). This would total $600,000 plus 50% overhead for a total of $900,000 per center. Thus, the initial 10 centers could cost approximately $9 million/year.

The other 40 centers would require more modest budgets for notification support. Assuming support for base staff and training activities of $250,000 per year, these other centers would require $10 million per year. This would include funding for a clinical coordinator, a training professional and a part-time physician. Alternatively, they could be provided only base support as a referral center for approximately $50,000 per year, or a total of $2 million per year for these additional centers.

III. RESEARCH ACTIVITIES

Much of the research would take place at the designated centers. However, there also could be an in-house effort to evaluate problems particularly in support of decisions on further notification efforts. These evaluations would focus on determining if specific occupational groups were at increased risk and required notification. This could include an intramural effort of $2.5 million annually plus an additional $2.5 million annually for further extramural research.

IV. NOTIFICATION EFFORTS

It is very difficult to estimate the costs of actual notification. This will depend on the application of the risk definition by the Risk Assessment Board, the types of industrial groups covered, the nature of these industries (small versus large), and the difficulty of selecting specific plants for the notification effort. Also, while actual notification costs will average approximately $33 per worker* (once the individual, potentially exposed workers are identified), the process of obtaining the necessary records and actually identifying the individual workers will vary depending on the nature of the industry, the availability of company personnel and demographic records, etc.

For example, small industries would be very expensive to locate and their records would be hard to obtain. However, these workers might be among those most in need of notification because of lack of previous hazard information and because of more severe exposures. Large industries may also present problems. For example, only a small number of workers may be exposed to a chemical at a large chemical plant. However, locating the records for these specific workers might require the review and data processing of all of the records at that facility. (See attached table for further details.)

Some notification efforts would require only small amounts of support. For example, there are only 2,000 workers who may have been potentially exposed to benzidine, as covered by the OSHA standard. This group could be notified for under $100,000.

However, other groups covered by the 23 OSHA standards (promulgated under Section 6(b)(5) of the Occupational Safety and Health Act) include many more workers. For example, we estimate that approximately 3.2 million workers were exposed to lead and lead compounds in 1971-1973. Of these, OSHA estimated that 800,000 were exposed in industries with a significant risk of problems with lead exposure. Assuming that half of these workers were appropriate for notification efforts (having left employment after significant exposure but still living) and that it would cost an average of $40-55 per worker to (1) select the industries and obtain the necessary records, (2) prepare the records for data processing (i.e., actually define individual workers potentially exposed), and (3) conduct the actual notification. The costs for just this group alone would be $16-22 million.

The other 2.4 million lead workers could require additional efforts. While fewer groups might be eligible for inclusion, considerable effort would still be required to determine which groups and individual workers to notify. Assuming the $40-55 cost and that only one-sixth of these workers would qualify, this would still require another $16-22 million. In addition, current workers would need to be notified. Assuming that this costs $5 per worker, and that 800,000 workers have significant exposure, this would cost an additional $4 million for workers in the lead industry.

In addition to the lead industry example cited above, there are many more industries which would be covered by the 23 OSHA standards referenced in the legislation which would be included in the bill's notification efforts. Therefore, the total cost of this legislation would be extremely large.

V. HOTLINE COSTS

Our estimates here are based on experiences with NIOSH hotlines and contacts with the telephone companies. For a base cost, to handle a hotline for one year with 400,000 calls, the estimate is approximately $55,000 annually.

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* See attached memorandum dated January 23, 1986.

VI. HEALTH CARE FINANCING SYSTEMS

These estimates do not include the costs to the public and private health care financing systems which would result from the testing, evaluation and medical monitoring required for workers subject to notification.

TABLE - ESTIMATED COSTS FOR NOTIFYING 100,000 WORKERS

SCENARIO A - MEDIUM-SIZED PLANTS WITH MOST OF THE PLANTS QUALIFYING FOR NOTIFICATION

STEP 1- Identify participating industries. Assuming 250 plants with 500 workers at each, but only 200 will qualify (80%). Also will be able to screen 60% by telephone leaving 100 to visit to assess exposures.

4 IH's** plus 1 clerical	$180,000
Travel-$500 times 100 visits	$ 50,000

STEP 2- Obtain records by microfilming visits (200 plants)

4 teams of 2 each plus clerical support (2)	$250,000
Travel	$ 75,000

STEP 3- Identifying individual, potentially-exposed workers and coding ($1.50 times 100,000)	$150,000
STEP 4- Notification ($33 times 100,000)	$3,300,000
TOTAL	$4,005,000 or

approximately $40.00/worker actually notified

SCENARIO B - SMALL PLANTS WITH ONLY HALF OF THE PLANTS QUALIFYING FOR NOTIFICATION

STEP 1- Identifying participating industries. Assuming 800 plants with 250 workers each, but only 400 qualifying. Will be able to screen 50% by telephone leaving 400 to visit to assess exposures.

10 IH's plus 2 clerical	$440,000
Travel-$500 times 400 visits	$200,000

STEP 2- Obtain records by microfilming visits (400 plants)

8 teams of two each plus clerical support (3)	$475,000
Travel	$150,000

STEP 3- Identifying potential exposed workers and coding ($1.50 times 100,000)	$150,000
STEP 4- Notification ($33 times 100,000)	$3,300,000
TOTAL	$4,715,000 or

approximately $47.00/worker actually notified

**NOTE: IH's = Industrial Hygienists

SCENARIO C - SMALLER PLANTS QUALIFYING FOR NOTIFICATION

STEP 1- 1,500 plants with average of 100 workers in each plant. Only 1000 will qualify (67%). Will screen 50% by telephone leaving 750 to visit.

16 IH's plus 3 clerical	$715,000
Travel-$500 times 750 visits	$375,000
STEP 2- Obtain records by microfilming visits (1,000 plants) 12 teams of 2 each plus clerical support (4)	$700,000
Travel	$250,000
STEP 3- Identifying potential exposed workers and coding ($1.50 times 100,000)	$150,000
STEP 4- Notification ($33 times 100,000)	$3,300,000
TOTAL	$5,490,000 or

approximately $55.00/worker actually notified

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date January 23, 1986

From Chief, Screening & Notification Activity, IWSB

Subject Estimated Cost for Notification

To James M. Melius
Director, DSHEFS
Through: Chief, IWSB ______ ______

At your request the following cost estimates for notification on a per subject basis have been developed. It is estimated that it would cost approximately $33 per subject.

Estimated Cost for Notification

Estimate based on 10,000 person cohort.

1.	Cohort location @ $0.19/subject	$ 1,900
	Special follow-up @ $2.00/subject	$ 4,000
2.	File update, coding letter preparation, hotline	$ 30,100
3.	Materials @ $2.50/subject	$ 25,000
4.	Personnel: year 1, 5 people @ $35,000	$175,000
	Year 2, 5 people for 0.33 year	$ 57,750
5.	Travel	$ 30,000
	Total for 10,000 subjects	$323,750
		$32.38/Subject

This estimate is based on assumptions previously specified in a document entitled "Organizational Plan: NIOSH "Notification Project" (Two Pilot Studies)". Follow-up would generally involve using data bases from the Social Security Administration, Internal Revenue Service and the Health Care Finance Administration. Twenty percent of subjects would be followed by means of retail credit checks.

This estimate differs from the estimate derived from the previous NIOSH pilot studies for the following reasons:

1) The Augusta study involved more extensive record preparation and vital status determination.

2) The Augusta study also involved a mortality analysis which necessitated obtaining death certificates and achieving greater than 95% follow-up. Generally notification is acceptable with as little as 75% follow-up.

3) The Augusta study had extensive research costs attached. It was very labor and time intensive due to its pilot status. Generally notifications will be more efficient and cost effective.

4) The Augusta study involved a small cohort therefore increasing the costs per subject because fixed costs were distributed over a smaller population than would be usually found in most notification efforts.

Paul A. Schulte

Senator **Metzenbaum**. Dr. Melius and Dr. Millar, I have listened to this face-saving testimony describing NIOSH's existing notification efforts as adequate. You and I know that Federal notification based on cohort mortality studies is inadequate; that fewer than 5,000 people have been notified since 1977, and that S. 79 will substantially improve occupational disease prevention in the United States.

As medical professionals, do you really have any disagreement with the testimony delivered by Dr. Landrigan?

Dr. **Melius**. We certainly would agree with his testimony that there is significant benefit from this type of notification and that it is feasible to do and certainly would benefit the people notified.

Dr. **Millar**. Mr. Chairman, I would like to add to that. Is there something specific in Dr. Landrigan's testimony that you wanted affirmed or not affirmed, or was it the general thrust?

Senator **Metzenbaum**. Well, I think the overall general thrust of his testimony is what my question encompasses, Dr. Millar.

Dr. **Millar**. Dr. Landrigan is a product of NIOSH of whom we are very proud, and I think that in general, he speaks along highly-skilled professional lines. So I think we can in general support what he had to say.

Senator **Metzenbaum**. I have run over my time, but I am going to give you extra time as well, Senator Quayle.

Dr. Windom, you have heard leading national figures in the field of occupational health testify that this bill is badly needed and that its focus on medical surveillance will save lives and money. You have heard your own agency's top expert in this area testify that S. 79 is both scientifically workable and financially responsible.

I ask you frankly, isn't it time for the Adminstration to sit down and work with the Congress to pass this bill, and don't you believe the Federal government should prevent disease and death when, as here, it is clearly in a position to do so? What bothers me is the intransigence of the Administration's position, almost a knee-jerk reaction, that, "Well, it has got something new, it is something having to do with new kinds of notifications, and with the general term of regulation, and therefore we will be opposed to it." But your own people are saying it is workable; the professionals in the field say it is needed. My real question is, why can't we work this out with the Administration? Why can't we move forward on a piece of legislation that is so badly needed in this country?

Dr. **Windom**. Mr. Chairman, I certainly feel that we can work together and can proceed to the goal of promoting health and preventing disease. I think as a result of this hearing now, that compared to last year, improvements have been made in the legislation and that discussions can go on between your staff and our Department. I think with the awareness that increases day-by-day and concern by industry, business and individuals themselves about health and about the need to improve health, people will become more aware of these problems. We can do much of this through the process which we have already established, and we will take advice and guidance and continue to do it through that mechanism.

Senator **Metzenbaum**. Well, we would like to work with you, Dr. Windom.

Dr. **Windom**. Thank you.

Senator METZENBAUM. I am happy to see that Senator Matsunaga has joined us.

Senator Quayle, do you have questions?

Senator QUAYLE. Yes, thank you, Mr. Chairman.

I certainly think that Dr. Windom's concluding statement in his testimony and the response that he has just given you shows a willingness to sit down and certainly discuss the issue. And I appreciate your willingness to look at the alternative proposal that we are going to be putting forward. I think it deals specifically with the very important issue of how we go about this whole notification process, to ensure that we use a scientifically valid approach and also who is going to be reviewing the data and how from a policy perspective, notification ought to take place.

Dr. Windom, is it your position that S. 79 sets up a scientifically sound procedure?

Dr. WINDOM. I think the procedure is, to the best I know the bill, scientifically sound. But I think also, our own NIOSH program is very scientifically sound through its Board of Scientific Counselors which actually is a larger group than the Board that is recommended here, and continues to evaluate their program scientifically.

Senator QUAYLE. Do you think it is scientifically sound to notify workers of these risks based on animal and laboratory studies?

Dr. WINDOM. Yes, under certain circumstances. I think there are situations where that is not across-the-board true and should not necessarily be in each instance. But there are places where it may be appropriate in certain circumstances.

Senator QUAYLE. There are cases where it would be appropriate and cases where it would not be appropriate.

Dr. WINDOM. Yes.

Senator QUAYLE. Dr. Melius, have you looked at our alternative approach at all? Have you had an opportunity to look at the outline of it?

Dr. MELIUS. Yes, I have.

Senator QUAYLE. What is your general assessment?

Dr. MELIUS. Well, certainly, for the populations involved there, which would be groups that would be covered by Federally-funded or Federally-conducted studies, the approach would essentially notify the type of populations we are trying to get at through the NIOSH approach.

As that approach was applied to this particular type of study, epidemiological studies, certainly, the criteria that could be developed might be much more specific than the criteria that are included in S. 79 now. It would be a more defined group, on a more defined database that one would be working with.

Within NIOSH, we have taken efforts in the last several years to develop these kind of criteria (working with our Board of Scientific Counselors) and also to develop an approach that would assure that for all new studies that we start, we include consideration of individual notification, or appropriate notification of the people involved in those studies if the findings of the study warrant that type of notification.

Senator QUAYLE. Do you think it is important, or would it facilitate our objective in this case, to establish the scientific review process of these particular studies?

Dr. MELIUS. I think it is very useful that that take place. Certainly for ourselves, we see that as being a very valuable input to our own decisionmaking on this. Even though our Board of Scientific Counselors came up with criteria that were quite close to what we proposed, during the two-day session where those were developed, we went back and forth and really gave some very serious consideration to how these guidelines should be developed. We now intend to go back to our Board of Scientific Counselors after we have applied the notification criteria to specific studies and get scientific peer review of this process.

Senator QUAYLE. Under S. 79, there is a provision which would give the Risk Assessment Board the authority to either conduct or provide for research in a variety of areas. This is a little bit different way of funding research. As a rule, grant-making is done through a process of scientific peer review.

What is your assessment, and could you comment on this new grant-making authority, that is in S. 79, or do you think the process of scientific peer review that we currently have is a preferable way to go about it?

Dr. MELIUS. I think the current system works very well. My interpretation of this approach was to fund certain types of scientific research relevant to this particular bill and that a mechanism could be set up for awarding those grants or funding that research that would include scientific peer review.

Senator QUAYLE. That is not specifically stated in there.

Dr. MELIUS. No.

Senator QUAYLE. And as a matter of fact, I am not certain how it would work. We would have to get into the details. But it struck me as I looked at it as certainly a change from our current system of awarding grants. I think the present peer review system is very objective, strikes me as a sensible way of awarding grants. If you put the research just under this Risk Assessment Board, we are really granting some rather new, broad authority, that I am not sure we want. And listening to you, I am not sure that you really want it to, either.

Dr. MELIUS. Yes. Well, certainly a peer review mechanism built into that process would benefit the conduct of that type of research.

Senator QUAYLE. Thank you.

Thank you very much, Mr. Chairman.

Senator METZENBAUM. Thank you very much, Senator Quayle.

Senator Matsunaga, we are happy to welcome you.

Senator MATSUNAGA. I believe Senator Harkin was here first.

Senator METZENBAUM. Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman.

Dr. Windom, I was just reading on page 4 of your testimony commenting on S. 79. Being a cosponsor of it and having more or less gone through it before, I was somewhat astounded by your comment that, "The bill would expose the United States and its employees to potentially enormous liability. This could result in substantial litigation, in many cases without merit, imposing enormous costs on consumers, workers, and the Federal government. In addition, this could add thousands of new lawsuits to the already-burgeoning tort dockets of the Federal courts."

However, Section 5(f), page 15 of the bill, specifically says, if I can read it for you because—I do not think it can be much clearer than this—"The Secretary and the agents of the Secretary, including any employer or government acting pursuant to Section 6"—which is the notification section—"shall not be liable under Federal or State law for monetary damages with respect to any omission or act performed pursuant to this section unless the omission or act is willful."

How is that going to open it up? That sounds to be pretty tight. It says that the government will not be liable, unless action was willful, in other words, someone knew, but they purposely did not give notice. This basically is the law today anyway, so it does not open it up any more than what we already have.

Dr. WINDOM. Well, then, I would have to defer to legal counsel on that. I was under the impression that there would be some areas that this would still create that possibility. I may stand corrected on that.

Senator HARKIN. Well, I just wanted to have you look at it with your legal counsel, because it seems to me that Section 5(f) is quite clear in that regard.

Then in the next paragraph of your testimony, on page 4, you say that, "We also note that the scope of the worker notification program envisioned by S. 79 may have an adverse influence on State workers' compensation programs because the fact that claimants have been notified by the Federal government that they are 'at risk' may be incorrectly interpreted to mean that disease in the claimant was caused by employment."

Again I would refer to Section 10(g) of the bill, if you want to copy that down, entitled "Effect on other Laws." Again I will read it for you. It seems to me very clear. "The notification of an employee pursuant to this Act that the employee is in a population at risk and the initiation of medical evaluation and monitoring shall not constitute or in any way affect a claim for compensation, loss or damage arising out of exposure to the occupational health hazard, except that the results of such medical evaluation and monitoring may be introduced as evidence with respect to such claim." Now, this is what I want to emphasize: "Notification pursuant to this Act shall not be relevant in determining whether such a claim is timely under any applicable statute of limitations."

Again what it says is that basically, the notification shall not constitute in any way or in any way affect a claim except that the results can be used, which is present law anyway.

So again, I do not see that it would have any effect at all on State workers' compensation programs. I mean, in terms of the workers' compensation programs in the States the bill left that whole just the way it is today.

So I again would ask you to look at that paragraph and check with your legal counsel, because I do not think they are quite right on that.

Dr. WINDOM. We will provide that for the record for you, Senator.

Senator Harkin. I would appreciate it if you would and let me know if there is something that I am not seeing in the clear language of the bill.

Dr. Windom. Yes, we will, sir.

Senator Harkin. Thank you very much.

Thank you, Mr. Chairman.

Senator Metzenbaum. Thank you, Senator Harkin, for the very astute line of questioning.

Senator Matsunaga.

Senator Matsunaga. Thank you, Mr. Chairman.

I apologize for my tardiness, but I was over at another hearing, a veterans' hearing.

Senator Metzenbaum. We are very happy to welcome you to the Committee whatever time you arrive, and also note that you are a cosponsor of the legislation.

Senator Matsunaga. As a cosponsor, Mr. Chairman, I am very much disturbed that the Administration still opposes the measure. I think, Dr. Windom, in your statement you say that you were strongly opposed previously, but of course, it would seem to indicate that you were not as strongly opposed as you were previously. But then, you still say that you continue to oppose the legislation.

Now, I hope in your statement here—I have not had a chance to go through it in detail as yet—that you offer specific suggestions as to how the bill can be amended in order that you may support the measures in toto.

Dr. Windom. Well, we certainly support your concern and we would continue to make the efforts to resolve these problems and to look into them and to prevent further problems in the future as best we can. But then, for example, there are some points I listed here where we do not support the bill, such as the establishment of additional occupational and environmental health centers. The training provisions of these new centers, we feel, would completely duplicate the existing centers that are already funded by our Department. So we feel that that would be an unnecessary extra addition.

We strongly oppose the provision mandating the specific curricula in the medical schools. We feel that that would certainly not be appropriate. The medical schools should have the right to add to curricula as they feel best, and further training would go beyond the medical school stage.

The bill also does not provide the Secretary of HHS with the power ultimately to determine which individuals should be notified, but leaves that decision with the Risk Assessment Board. We feel that this would put an independent authority below the level of the Secretary. Our present system of a board of scientific advisors, we feel, is carried out well.

Senator Matsunaga. But you do feel that there is a problem here which cries for solution?

Dr. Windom. Yes. We are approaching that problem. We are looking at the studies, and will go back and evaluate the approximately 15 that seem to be most relevant out of the 90 that are retrospective studies. We have plans underway to review those and are taking steps to do that.

So we are looking into it, Senator.

Senator **Matsunaga**. Thank you, Mr. Chairman. I do not wish to take any more time.

Senator **Metzenbaum**. Thank you very much, Senator Matsunaga.

I want to say thanks to the panel, and I will indicate to you as I indicated to the previous panel, some of the members may have questions that they wish to submit in writing, and I feel certain that you will be willing to make your responses in writing.

Thank you very much.

[Responses of Dr. Windom to questions subsequently submitted by Senator Hatch follow:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

MAR 27 1987

The Honorable Howard Metzenbaum
Chairman, Subcommittee on Labor
Committee on Labor and Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Metzenbaum:

In response to your letter of March 2, enclosed are the responses to Senator Hatch's questions concerning S. 79, the High Risk Occupational Disease Notification and Prevention Act, for insertion in the record of the February 24 hearing.

In addition, during the course of my testimony at the hearing, Senator Harkin highlighted certain issues that I promised to address in greater detail at a later date. Specifically, Senator Harkin questioned two statements in my prepared text, one dealing with potential tort liability ramifications of the bill and the other with the effect that the bill may have on the various workers' compensation programs.

During my testimony, I stated that S. 79 would expose the United States and its employees to potentially enormous tort liability. Senator Harkin questioned the accuracy of that statement and noted that Section 5(f) of the bill specifically provides that the "Secretary and the agents of the Secretary, including any employer or government acting pursuant to Section 6 shall not be liable under Federal or State law for monetary damages with respect to any omission or act performed pursuant to this section unless the omission or act is willful." Senator Harkin then stated that "[t]hat sounds to be pretty tight." However, the Department's Office of General Counsel informs me that the tort immunity contained in Section 5(f) is anything but "pretty tight" and is in fact, largely illusory for three reasons. First, the immunity provision of the bill extends only to actions taken under Section 5. There is nothing in S. 79 that would in any way limit the government's liability with respect to actions (or inactions) taken under the other sections of the bill. Indeed, the limited immunity provided by Section 5(f) by implication provides a positive basis for tort liability with respect to the actions of the Board under Section 4 in identifying populations at risk. Thus, if the Board were to determine that a given population were not at risk, then a member of that population could in theory institute an action against the government under the Federal Tort Claims Act, alleging that had the given population been identified, he, as a member of that population, would have been notified and thus, would have been put on notice to seek immediate medical treatment. Second, the immunity provision only extends protection to the "Secretary and the agents of the Secretary," and thus, by implication excludes other government officials, such as the Secretary of Labor and the Administrator of the Environmental Protection Agency, who may necessarily become involved in implementing the legislation. And third, the notion that liability could only be imposed if the Secretary's conduct were willful provides little, if any real protection. The term "willful" merely means that an action was intentional; it does not mean that an actor must have intended to violate the law. Thus, if the Secretary, acting under Section 5 of the bill, were to adopt a system of notification that was 99.99% effective, those few workers that were not notified, could in theory institute a suit notwithstanding the provisions of Section 5(f). Such a suit would allege that the Secretary knowingly (i.e., willfully) adopted a notification system that was less than perfect. In short, the immunity provisions contained in S. 79 do not afford the government adequate protection from suit.

In my prepared text, I also expressed concern that the bill may adversely affect various State compensation programs. Senator Harkin disagreed, noting Section 10(g) specifically provides that "notification of an employee pursuant to this Act ... shall not constitute or in any way affect a claim for compensation ..." The Senator concluded by observing that the bill would have no "effect at all on State workers' compensation programs." Once again, I must respectfully disagree with the Senator's interpretation. First, Section 10(g) only speaks to the issue of "notification" and does not address the determination that an individual is in fact a member of a population at risk. A second, Section 10(g) does not explicitly preempt State law; thus, notwithstanding the provisions of Section 10(g), a State compensation board could in fact consider as evidence the fact that a given worker was notified.

I appreciate the opportunity given to me to fully address the issues discussed above.

Sincerely yours,

Robert E. Windom, M.D.
Assistant Secretary for Health

Enclosures

1. Question: Would you or the Justice Department comment on the effect S. 79 would have on private liability, for example what would it do to the number of suits filed and what effect would the notices have on burdens of proof?

   Answer: The Department of Health and Human Services has no way of estimating the effect this legislation would have on private liability suits. The Department of Justice may have some basis for making this estimate. In the case of the lawsuits brought by the workers in Augusta, Georgia, after the NIOSH pilot worker notification study, all were dismissed by the Georgia Supreme Court.

2. Question: Could you provide us with a total cost estimate for S. 79, including notification cost for the Federal government and the private sector, medical screening and follow up costs, and increased liability costs? How would this estimate change if all employers exercised their option and left notification of their past and present employees to the Federal government?

   Answer: The total costs for the Federal government of a worker notification program are $ 26.2 - 42.8 million and 67 FTEs. The detailed outline is given in Attachment 1. These estimates assume that the notification would be the total responsibility of the Federal government. In calculating medical screening and follow-up costs, if one assumed $100 per worker (which may well be a low estimate), the cost would range from $10 million to $30 million, depending on the targeted number of workers notified. Further, it should be noted that the dollars and FTE's necessary to cover the legal services that will be required as a result of this legislation are not included.

3. Question: A great deal of the discussion on S. 79 has centered around its scientific validity. As I understand the scientific criteria, one animal study would be enough to require notification of a large human population, or one study which exposed a small number of subjects to a large dose might be enough to require notification of individuals who are only exposed to low doses, or a study based on long term exposure could require notification of workers who only have a short exposure time. Would you consider those examples I just listed acceptable scientific criteria for notification? You might also have the Justice Department comment on how a court challenge to required notification based on this type of scientific evidence would fare?

   Answer: From a scientific standpoint, the Department believes that the basis for notification decisions provided in S. 79 is seriously flawed. In S. 79, an extrapolation of one "statistically significant" study indicating that "acute or chronic health effects may occur in exposed employees" could trigger a potentially massive, inappropriate notification effort. Such studies could range from clinical and epidemiological studies to a single animal study. We recognize that animal studies can report significant findings that may provide indications of adverse health effects in humans. However, from a scientific standpoint, single studies--animal or human--may not be sufficient, without further confirmation, to initiate a program of such consequence as worker notification. The questions of how a court challenge to required notification would fare should be referred to to the Department of Justice.

4. Question: How scientifically sound would you consider a mandate that a minimum number of workers be targeted for notification, regardless of the scientific evidence available? What would HHS do if it found itself in a situation where there was only scientific evidence available to justify notification of 50,000 workers, but the law required them to notify 100,000? Would they hold the first annual HHS lottery?

   Answer: After initial implementation of the law, the target of 100,000 workers may be difficult to reach and would seem to be arbitrary and capricious. The Department certainly would not propose notifying workers simply to meet a target.

5. Question: S. 79 sets up a 5 member board within in the Public Health Service. This has been criticized for a number of reasons, including the fact the a 5 member board cannot have all the expertise necessary to evaluate the diversity of occupational health hazards which may present themselves. Do you have any comments on this?

   Answer: The vagueness regarding the Board's expertise as defined by the legislation could cause problems in reviewing information on particular substances. Presumably the Department, in implementing this bill, would have to provide for appropriate consultation and scientific peer review to overcome this deficiency. Such review may be impossible to accomplish within the proposed statutory deadlines.

Senator METZENBAUM. Our next panel consists of Mr. Howard Samuel, President of the Industrial Union Department of the AFL-CIO; Mr. Michael J. Wright, Director of Safety and Health, United Steelworkers of America; Mr. Robert Watson, Recording Secretary, United Steelworkers of America Local 1066, of Gary, Indiana; and Mr. George Cafasso, Safety and Health Committee Chairman, United Steelworkers of America Local 1557, of Clairton, Pennsylvania.

I do want to say to Mr. Watson that Senator Quayle wanted me to specifically indicate to you that he had hoped to be present. He was called away and hopes to be able to get back, but did want to hear your testimony and certainly to welcome you to the Committee.

Our time is running short. I understand Peg Seminario is sitting in for Mr. Michael Wright. I am going to ask you each to confine your remarks to five minutes, but if you can do it in less time than that, you get brownie points from the Chairman.

Mr. Samuel, we are happy to hear from you.

STATEMENT OF HOWARD D. SAMUEL, PRESIDENT, INDUSTRIAL UNION DEPARTMENT, AFL-CIO, ACCOMPANIED BY DAVID MALLINO, LEGISLATIVE DIRECTOR; MARGARET SEMINARIO, ASSOCIATE DIRECTOR, DEPARTMENT OF OCCUPATIONAL SAFETY, HEALTH AND SOCIAL SECURITY, AFL-CIO; ROBERT WATSON, RECORDING SECRETARY, USWA LOCAL 1066, GARY, IN, AND GEORGE CAFASSO, SAFETY AND HEALTH COMMITTEE CHAIRMAN, USWA LOCAL 1557, CLAIRTON, PA

Mr. SAMUEL. Thank you, Mr. Chairman. I will try to earn a couple.

My name is Howard Samuel, and I am President of the Industrial Union Department, AFL-CIO, which represents 53 affiliated unions with some 5 million members.

Let me say at the outset that organized labor, as well as the entire public health and environmental community, strongly supports S. 79.

Unfortunately, the bill has been the subject of misinformation and misrepresentation by its opponents, particularly in the Reagan Administration. Some of those comments and opposition were disclosed in a letter that was sent to the House of Representatives late last year; some were repeated today in the testimony by the Administration representatives. Let me just take a couple of minutes to refute a few of them.

Number one, contrary to the claim that the Department of Health and Human Services is already doing "risk assessments", the interagency committee that has been formed on risk assessment is merely a study group to determine how risk assessment should be conducted. It is not designed to implement a program, which is the purpose of the Risk Assessment Board created by S. 79.

Number two, contrary to the allegation that the bill would lead to increased litigation, there is absolutely nothing in S. 79 that either adds to or subtracts from the legal rights that workers or anyone else now have to sue for health damages caused by toxic substances. The Administration knows this and is merely using the litigation issue as a scare tactic.

As a matter of fact, since the program is geared to prevent disease through health promotion and medical surveillance, fewer medical cases and therefore fewer legal cases can be expected.

I think the Senator from Iowa has already disposed of the claim that the bill would place the U.S. government at increased risk of liability and also has disposed of the suggestion that it would have a deleterious effect on State workers' compensation boards.

Fourth, contrary to the claim that the bill's notification provisions are not technically feasible and will cost "hundreds of millions of dollars", every non-Administration professional to examine the bill has agreed that such notification can in fact be done.

In terms of cost, as we have already heard this morning, the bill caps the entire program at a mere $25 million per year and no more. It should be noted that the Federal government is now paying some $3.5 billion a year for occupational disease from Social Security disability, Medicare and Medicaid. The purpose of S. 79 is to prevent disease and reduce health care costs.

Fifth, contrary to the statement that the criteria for identifying workers for notification are not justifiable on a scientific or public health basis, the scientific criteria spelled out in the bill have been endorsed by the American Cancer Society, the American Lung Association, and the American Public Health Association, as well as by a number of distinguished individuals in the health field.

Sixth, contrary to the claim that the current OSHA Hazard Communication Standard already provides for notification, let me point out that the OSHA standard applies to only some current workers and current exposures and does nothing for employees who have already been exposed and who are at the highest risk of disease, and it does nothing for former employees, generally. It is the latter group who are the focus of S. 79.

The OSHA standard also provides no information on appropriate medical surveillance for workers at high risk of occupational disease.

For the record, Mr. Chairman, I would like to submit as an attachment a memorandum produced by my office which further details precisely what this bill does and does not do. We believe it is a good bill, it is a sound bill, and if enacted into law will go far to improve public health in the United States. It should be debated on its merits and not on trumped up misrepresentations and unfounded claims. Rather than attacking this bill, what the Administration should be doing is working with the Congress in an effort to ensure that this program achieves its goal of disease prevention and health care cost savings.

Let me introduce on my right, the Legislative Director of the Industrial Union Department, David Mallino, who has been very much involved in devising this bill.

Thank you.

Senator METZENBAUM. We are very happy to have Mr. Mallino join you this morning, Mr. Samuel, and we very much appreciate your comments.

[The prepared statement of Mr. Samuel follows:]

Statement of the Industrial Union Department, AFL-CIO

By Howard D. Samuel, President

On S. 79, The High Risk Occupational Disease Notification and Prevention Act of 1987

Before the Subcommittee on Labor

Of the Committee on Labor and Human Resources

United States Senate

February 24, 1987

Industrial Union Department, AFL-CIO
815 Sixteenth Street, N.W., Washington, D.C. 20006
202/842-7800

Howard D. Samuel, *President*
Elmer Chatak, *Secretary-Treasurer*

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Mr. Chairman, members of the committee, my name is Howard D. Samuel and I am president of the Industrial Union Department (AFL-CIO) which represents 53 affiliated unions with some five million members.

At the outset let me say that organized labor, as well as the entire public health and environmental community, strongly supports S. 79, the High Risk Occupational Disease Notfication and Prevention Act. We believe that this bill is essential if we, as a nation, are to successfully address the complex set of problems associated with occupational disease in the United States, including the ever-increasing health care costs of both the government and private industry.

This bill before you provides workers with the fundamental right to know that they are at high risk of disease because of previous exposures to toxic substances. It is a basic self-defense measure that will provide workers with the essential information to permit them to take the kinds of actions necessary to either prevent disease from occurring in the first place, or to detect it early enough for treatment.

Unfortunately, the bill has been the subject of misinformation and misrepresentation by its opponents, including the Reagan Administration.

In the closing days of the last Congress, when it appeared that the high risk bill might be considered in the House, the Secretaries of Labor and of Health and Human Services and the Attorney General wrote Chairman Joseph Gaydos detailing their objections to the bill. Since the new bills — although somewhat modified — are essentially the same as last year's bills, and since the Administration's claims have never been fully addressed, I would like to devote the remainder of my testimony to a point-by-point response to those allegations.

1. Contrary to the claim that the Department of Health and Human Services (HHS) is already doing "risk assessments," the interagency committee that has been formed on risk assessment is merely a study group to determine how risk assessments should be conducted. It is not designed to implement a program to "identify and designate populations of workers at high risk of disease," which is the purpose of the risk assessment board created by S. 79.

2. Contrary to the allegation that the bill would lead to increased litigation, there is absolutely nothing in S. 79 that either adds to or subtracts from the legal rights that workers or anyone else now has to sue for health damages caused by toxic substances. The Administration knows this and is merely using the litigation issue as a scare tactic. As a matter of fact, since the program is geared to prevent disease through health promotion and medical surveillance, fewer medical cases and therefore fewer legal cases can be expected.

3. Contrary to the suggestion that the bill would place the U.S. government at increased risk of liability for failure to notify, S. 79 very specifically states that there is no such liability and the government is held harmless and protected from such suits.

4. Contrary to the claim that the bill's notification provisions are not technically feasible and will cost "hundreds of millions of dollars," every non-administration professional to examine the bill has agreed that such notification can in fact be done. These include, former NIOSH Administrators Dr. John Finklea and Dr. Anthony Robbins, former OSHA Assistant Secretaries Dr. Eula Bingham and Dr. Morton Corn, and former National Cancer Institute Director Dr. Arthur Upton. In terms of notification costs, the bill caps the entire program at a mere $25 million per year and no more. It should

be noted, that the federal government is now paying some $3.5 billion a year for occupational disease from Social Security Disability, Medicare and Medicaid. The purpose of S. 79 is to prevent disease, and reduce health care costs.

5. Contrary to the statement that the criteria for identifying workers for notification "are not justifiable on a scientific or public health basis," the criteria were developed by three of the best epidemiolgists in the world, Dr. Irving Selikoff, Dr. Philip Landrigan, and Dr. William Nicholson of the Mt. Sinai School of Medicine. Moreover, the scientific criteria spelled out in the bill have been endorsed by the American Cancer Society, the American Lung Association and the American Public Health Association, as well as Drs. Upton, Bingham, Finklea, Robbins, and Corn.

6. Contrary to the claim that the current OSHA hazard communication standard already provides for notification, the OSHA standard applies to only some current workers and current exposures and does nothing for employees who have already been exposed and who are at the highest risk of disease, and it does nothing for former employees. It is the latter group who are the focus of S. 79. The OSHA standard also provides no information on appropriate medical surveillance for workers at high risk of occupational diseases.

7. Contrary to the allegation that occupational exposure information is already available to workers through existing OSHA standards, this information is only available in limited form to some current workers for current exposures, and only on a few chemicals (less than 20). No formerly exposed workers are covered by these OSHA standards. The same is true for their allegation with respect to the availability of medical surveillance for former workers.

For the record, Mr. Chairman, I would like to submit as an attachment a memorandum produced by my office which further details precisely what this bill does and does not do.

This is a good bill. It is a sound bill and if enacted into law will go far to improve public health in the United States. We believe that it should be debated on its merits and not on trumped up misrepresentations and unfounded claims. Rather than attacking this bill, what the Administration should be doing is working with the Congress in an effort to ensure that this program achieves its goal of disease prevention and health care cost savings.

Industrial Union Department
AFL-CIO

Howard D. Samuel, President
Elmer Chatak, Secretary-Treasurer

815 16th Street N.W.
Washington, D.C. 20006
202/842-7800

January 6, 1987

MEMORANDUM

TO: Members of Congress

FROM: Howard D. Samuel, President
Industrial Union Department, AFL-CIO

David Mallino, Legislative Director
Industrial Union Department, AFL-CIO

SUBJECT: **H.R. 162/S. 79, The High Risk Occupational Disease Notification and Prevention Act**

The Congress will shortly consider H.R. 162 and S. 79, the High Risk Occupational Disease Notification and Prevention Act. This bill provides workers with a fundamental right to know that they are at high risk of occupational disease because of previous exposures to toxic substances. It is a basic self-defense measure that will provide high risk workers with essential information that will permit them to take the kinds of actions necessary to prevent or early detect cancer and other diseases.

Unfortunately, the bill has been the subject of misinformation and misrepresentation by its opponents.

The purpose of this memorandum is to outline precisely what this bill does and does not do.

WHAT THE BILL DOES

1. **Identifies Workers At High Risk of Occupational Disease** — Through very careful review of epidemiological studies, a Risk Assessment Board created in the Department of Health and Human Services will identify populations and sub-populations of workers who are at high risk of disease because of previous occupational exposures. The exercise is based upon accepted epidemiological and biostatistical methods that have long been used. In determining what worker populations are at high risk, the House bill directs the Board to isolate those exposed worker groups where the incidence of disease is 30 percent greater than the non-exposed general population. This 30 percent trigger has been developed by Dr. Irving Selikoff and Dr. William Nicholson of Mt. Sinai Hospital in New York, two of the world's leading epidemiologists and biostatisticians. The Senate bill does not include the 30 percent trigger but directs the Board to make its determination on the basis of "statistically significant" evidence based upon at least one study conducted in accordance with established scientific principles.

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2. **Notifies Workers at High Risk of Occupational Disease** — Once a worker population at high risk has been identified by the Risk Assessment Board, the Secretary of Health and Human Services will undertake to notify each individual within the population of their risk of disease. The techniques for such notification are well-established within HHS and its National Institute for Occupational Safety and Health (NIOSH) which has conducted a number of pilot worker notification programs. The contents of the notification will basically include all the scientific and medical information that a worker and his family physician needs to know to begin monitoring the worker's health status. It should be noted that not all workers exposed to a given toxic substance will or should be notified because not all exposed workers are at risk. Again, the bill is aimed at only those specific sub-populations of workers who exhibit a greater increased incidence of disease compared to the general population. Thus, without this increased incidence of disease there would be no notification even though there were known exposures. The only exception might be where the Risk Assessment Board determines that overwhelming clinical evidence of disease demands such notification.

3. **Counsels Workers at High Risk of Occupational Disease** — One of the key elements of the proposed program is medical counseling. A primary component of the worker notification is a recommendation that he place himself on a medical surveillance program and take certain health promotion measures in an effort to prevent the disease from occurring. The purpose of medical surveillance and health promotion — especially when the worker and his family doctor knows he is at high risk — is to either prevent the disease altogether or to detect it early enough for successful treatment. In a number of cases, it is known that certain health promotion measures such as smoking cessation and dietary changes can greatly increase an at risk worker's chances of disease prevention. In other cases, such as chemically induced bladder cancer, if detected in its initial manifestations can be successfully treated. If, as is mostly the case today, bladder cancer goes undetected at its early stages, then the disease is nearly always terminal. In addition to the human suffering that could be avoided through early detection the costs of monitoring for bladder cancer are about $100 per year compared to $30,000 to $50,000 for basically warehousing bladder cancer patients until they die. The costs of any medical surveillance are to be borne either by the employer who exposed the worker (as is the case today under all OSHA health standards) or, if there is no such employer, by the worker himself through his existing health care program.

4. **Provides Technical Assistance to Local Medical Community** — The Occupational and Environmental Health Centers established by the bill are existing health care and research facilities with a demonstrated expertise in occupational and environmental health. After they are certified as such by the Secretary of HHS, their principal function is to serve as a technical resource to local health and medical communities. It is expected that upon receipt of the notification, the worker will consult his own family physician who, in turn, can consult with the Center in his area as to the manner and type of medical monitoring most appropriate for the patient. Most, if not all, of the medical surveillance will be conducted by either the family doctor or through existing employer provided programs.

5. **Provides Additional Research** — The bill provides for research to be conducted by HHS into additional epidemiological studies of exposed worker populations, improved means of early disease detection and health promotion and better treatment of occupational diseases.

6. **Worker Anti-discrimination Protection** — The bill provides strong anti-discrimination protections for workers who are notified that they are at high risk of disease. These protections are necessary because workers at increased risk must feel free to place themselves in medical monitoring programs without the fear of losing their job or existing insurance coverage.

7. **Provides for Outside Input and Judicial Review** — In order to ensure that the Risk Assessment Board has the best information and research available, the bill provides for written notice and comment on any proposed recommendation of the Board as well as public hearings if requested by any interested party. Any party adversely affected by decisions of the Secretary of HHS has the right of judicial review.

8. **The Bill is Supported by a Broad Range of Public Health, Labor and Environmental Groups and Professionals** — Included in the groups supporting the bill are the American Cancer Society, the American Lung Association and the American Public Health Association. They have been joined in this support by the entire labor movement as well as the Sierra Club, Audubon Society, Public Citizen, Citizen Action and the OSHA/Environmental Network. In addition a number of leading occupational and environmental health professionals expressed support for the bill, including Dr. Irving J. Selikoff, Dr. William Nicholson, and Dr. Philip Landrigan all of Mt. Sinai in New York; Dr. John Finklea, former Director of NIOSH; Dr. Eula Bingham, former OSHA Assistant Secretary, Dr. Nicholas Ashford of Harvard University, and Dr. Author Upton, former director of the National Cancer Institute.

WHAT THE BILL DOES NOT DO

1. **Does Not Duplicate the OSHA Right-to-Know Standard** — The OSHA Hazard Communication standard is designed to warn workers of the hazards of existing chemicals in the workplace. Unlike H.R. 162 and S. 79, it does not seek to isolate those workers at particular high risk because of previous exposures and inform them of the risk. Moreover it does not provide for medical counseling and monitoring which is a major component of H.R. 162 and S. 79. Further, the OSHA standard does not cover former employees (many of whom are at the highest risk) or major sectors of the current workforce such as public employees and those engaged in the transportation industry. Thus, the H.R. 162/S. 79 program is a critical supplement to the OSHA standard and not duplicative at all.

2. **Does Not Create a "Large New Bureaucracy"** — The only new government unit created by H.R. 162/S. 79 is the nine-member Risk Assessment Board chaired by the Assistant Secretary for Health and composed of five existing HHS career public health officers and three private physicians with some expertise in occupational health.

3. **Does Not Involve Large Sums of Federal Funds** — The entire program is capped at an annual $25 million authorization and the preliminary Congressional Budget Office cost estimate ranges from $15 million in the first year to about $27 million in the fifth year. In addressing the cost issue some other cost considerations must be kept in mind. First, according to the Social Security Department, occupational disease costs the Social Security Disability program about $2.5 billion annually. Thus, a very modest program designed to prevent occupational disease in the future will have a large payoff in not only reducing the Social Security Disability costs but also in the associated costs of Medicare, Medicaid as well as private health care costs.

4. **Does Not Create Any New Tort Liability Standards** — H.R. 162/S. 79 neither adds to nor substracts from the legal rights that currently exist for workers and other citizens who may be damaged by a responsibile party. As a matter of fact the bill specifically states that mere worker notification of disease risk does not have any standing in tort law or in any subsequent workers compensation claim. Frankly, the program, by preventing new cases of occupational disease, should have a long term affect on reducing toxic tort cases as well as workers compensation costs. Moreover, the federal government and any employer who voluntarily seeks to notify workers under the bill are held harmeless for any failure to warn under existing tort law.

5. **Does Not Impose any New Regulatory Burdens on Business** — The bill does not require employers to do anything except to bear the costs of medical surveillance if they were the employer responsible for the exposure. This is not a new cost since employer provided medical surveillance is already required in all health standards issued under the Occupational Safety and Health Act. For those employers who wish to notify, counsel and provide medical monitoring for the employees, the bill has a provision for them to do so under a simple certification procedure.

Senator METZENBAUM. Our next witness is Ms. Seminario, speaking in behalf of Michael Wright, Director of Safety and Health for United Steelworkers of America.

Ms. SEMINARIO. Thank you very much, Mr. Chairman.

My name is Margaret Seminario. I am Associate Director for the Department of Occupational Safety, Health, and Social Security for the AFL-CIO. As you have indicated, I am filling in for Mr. Michael Wright, who is the Director of Health and Safety for the Steelworkers Union, who unfortunately is unable to be here today.

I would like to take just a few minutes to summarize Mr. Wright's testimony to serve as introduction primarily for the testimony we will soon hear from Mr. Watson and Mr. Cafasso, who are Local Union members from the United Steelworkers of America.

The United Steelworkers of America supports S. 79. The Union believes it is a necessary piece of legislation to assist workers who are at increased risk of disease due to occupational exposures. Through notification, medical surveillance can be done; we can cure occupational diseases. For others, the symptoms can be ameliorated and the lifespan of these workers extended.

Today, the testimony of two individuals who are here will give an example of the need and the benefit of such a notification and prevention program, both for hazards that have long been recognized—and also for cases where the risk of disease due to exposure is more recently developed as new scientific studies are conducted and we find out that there are in fact additional hazards in the workplace.

Mr. George Cafasso works in a plant making metallurgical coke. Benzene is an important byproduct of the coking operation. Mr. Cafasso's plant recovers benzene and sells it as a feedstock to other chemical industries. Benzene can cause leukemia and a number of other blood disorders--a fact which has been known since 1897, since the first case reports with respect to benzene induced leukemia were first reported.

After years of petitions, hearings and litigation, OSHA hopefully is about to set a new benzene standard. While the standard will probably require notification, training and periodic blood tests for currently exposed workers, it will contain no such provisions for workers who have retired or changed employers. Indeed, during the standard setting hearings, OSHA stated it was its belief that the agency had no authority to require any such measures for workers who have retired or since changed jobs.

This bill could help those thousands of former benzene workers get the information and medical help they need to reduce the risk to their lives.

The legislation could also help prevent such tragedies in the future. Mr. Bob Watson can speak to that issue from his own experience. Mr Watson works in the pickling department of a large steel mill. Pickling is the process of removing grease and mill scale formed on steel sheet during hot rolling, using an acid bath. Workers in the pickling house are exposed primarily to acid mist. It has long been known that high exposure to acid mist can cause irritation of the eyes, nose and throat and deterioration of the teeth.

It has been suspected that certain acids might cause an increase in throat and lung cancer, perhaps by interacting with other carcinogens present in air pollution or in cigarette smoke. But no definitive studies were completed until last year.

In August of 1986, James Beaumont and other investigators at the National Institute for Occupational Safety and Health released a study of "Lung Cancer Mortality in Workers Exposed to Sulfuric Acid Mists and other Acid Mists in Steel Pickling Operations." The study demonstrates a statistically significant increase in lung cancer among such workers. The study is awaiting publication.

Workers exposed to acid mist deserve to know the risk to their health. They deserve proper medical surveillance and good explanation of the steps they can take to reduce the risk of cancer.

It will be years before OSHA can set a new acid mist standard, and that standard if set will apply only to workers then exposed.

The Steelworkers Union will be undertaking an effort to notify pickling house workers and other current and former members exposed to acid mist. They will also be attempting to negotiate medical surveillance provisions for current employees, although bargaining is not scheduled for several years.

Unfortunately, the companies are not obligated to bargain with the union over benefits for former workers. Even then, the Union represents only a small minority of workers exposed to acid mist. Many of these workers have no representation. Only a comprehensive Federal program like the one contained in S. 79 can reach all workers in a uniform and effective manner.

Thank you.

Senator METZENBAUM. Thank you very much.

[The prepared statement of Mr. Wright follows:]

TESTIMONY OF

MICHAEL J. WRIGHT
DIRECTOR, SAFETY AND HEALTH
UNITED STEELWORKERS OF AMERICA

before the

LABOR SUBCOMMITTEE
of the
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

on the

HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT
S.79

TUESDAY, FEBRUARY 24, 1987
WASHINGTON, DC

Senator Metzenbaum, members of the Subcommittee:

Thank you for the opportunity to appear before you in support of this important legislation.

My name is Michael J. Wright. I am a member of the United Steelworkers of America and direct the union's Safety and Health Department. With me today are two other members of our union -- George Cafasso, Safety and Health Chairman of our Local 1557 in Clairton, Pennsylvania, and Robert Watson, the Recording Secretary of our Local 1066 in Gary, Indiana.

The USWA is the collective bargaining representative of approximately 600,000 workers currently employed in the United States. Many of them are exposed to highly toxic materials in the course of their work. We are, of course, here today on their behalf, but we are also here on behalf of the 500,000 Americans who are former members of our union. Many of them lost their jobs in the economic recession afflicting our basic manufacturing industries. Others are retired or disabled or have simply moved to other jobs. Many of these workers and former workers were also exposed to toxic materials in the past. Since occupational disease may develop years after first exposure, many of them continue to face a high risk of work-related illness. In some cases, they know the risk; but all too often, they do not. Many of these diseases can be cured through early diagnosis and treatment. Even where the disease is incurable, a person's symptoms can be ameliorated and his or her life span extended through early intervention. Workers who know they are at risk can often take important measures of their own to reduce the risk, like quitting smoking in the case of former asbestos workers. Yet, none of these steps can be taken unless an individual knows that he or she is at risk. The OSHA Hazard Communication standard requires that some workers be told the hazards of the chemicals they currently use on the job. Nevertheless, the bill would greatly benefit these workers by requiring additional notification, and by establishing a system for medical follow-up. The bill has even greater benefits for workers formerly exposed to hazardous chemicals. No federal law or regulation requires that these persons be told of the risk to their health or provided with appropriate medical surveillance. A few OSHA standards, for example, mandate medical surveillance for currently exposed workers. But that surveillance ceases on the day the worker leaves his or her job -- despite the fact that the disease in question may develop twenty years later. Senate Bill 79 would help remedy that situation.

The union brothers appearing with me can provide examples of the benefits of such a program. George Cafasso works in a plant making metallurgical coke. Benzene is an important by-product of the coking operation. The plant recovers benzene and sells it as a feedstock to the chemical industry. Benzene causes leukemia and a number of other blood disorders, a fact which has been known since 1897. After years of petitions, hearings, and litigation, OSHA is about to set a new benzene standard. While the standard will probably require notification, training, and periodic blood tests for currently exposed workers, it will contain no such provisions for workers who have retired or changed employers. Indeed, during the hearings OSHA stated its belief that it has no authority to require any measures for workers who have retired or changed jobs. This bill could help thousands of former benzene workers get the information and medical help they need to reduce the risk to their lives. If the OSHA standard is delayed, as most OSHA standards are, the bill will benefit current workers as well. Unfortunately, it will come far too late for many workers, as Mr. Cafasso will shortly testify. The tragedy is that with proper notification and medical follow-up, many of these workers might be alive today.

This legislation could help prevent such tragedies in the future. Bob Watson can speak to that issue from his own experience. Mr. Watson works in a pickling department of a large steel mill. Pickling is the process of removing grease and mill scale formed on steel sheet during hot rolling, using an acid bath. Workers in the pickling house are exposed primarily to acid mist. It has long been known that high exposure to acid mist can cause irritation of the eyes, nose, and throat, and deterioration of the teeth. It has been suspected that certain acids might cause an increase in throat and lung cancer, perhaps by interacting with other carcinogens present in air pollution or cigarette smoke. But no definitive studies were completed until last year. In August, James J. Beaumont and other investigators at the National Institute for Occupational Safety and Health released a study of "Lung cancer mortality in workers exposed to sulfuric acid mists and other acid mists in steel pickling operations." It demonstrates a statistically significant increase in lung cancer among such workers. The study is awaiting publication.

Workers exposed to acid mists deserve to know the risk to their health. They deserve proper medical surveillance and a good explanation of the steps they can take to reduce the risk of cancer. But it will be years before OSHA can set a new acid mist standard, and that standard, if set, will apply only to workers then exposed. Our union is undertaking to notify pickling house workers and other current and former members exposed to acid. We will also attempt to negotiate medical surveillance provisions for current employees, although our next round of bargaining with many companies is not for three more years. Unfortunately, the companies are not obligated to bargain with us over benefits for former employees. Even then, we represent only a small minority of workers exposed to acid mists. Many have no union representation at all. Only a comprehensive federal program like the one contained in S.79 can reach all workers in a uniform and effective manner.

Thank you again for the opportunity to testify. I would be happy to answer any questions, but with your permission, I would prefer to wait until after the testimony of Mr. Cafasso and Mr. Watson.

Senator **Metzenbaum**. Mr. Robert Watson, Recording Secretary of the United Steelworkers, from Gary, Indiana.

Mr. **Watson**. Senator Metzenbaum, members of the Subcommittee, I would like to thank you first of all for the opportunity to present my views in support of S. 79. My name is Robert Watson. I am the Recording Secretary of Local Union 1066 of United Steelworkers of America, in Gary, Indiana.

For the past 23 years, I have been employed in the continuous pickling department of a major steel producer. In these 23 years, I have been exposed to a series of acids and chemicals used in this operation. The acids, sulfuric and hydrochloric, were at times enhanced by various chemicals, and at other times, different substances were used to retard the acids or the fumes caused by them.

In addition to the acid, many experimental processes have been tried. These processes were aimed at retarding rust or enhancing drawing properties by applying various types of external coatings.

Added to these is the constant spray of regular coating oils, some petroleum-based, others animals-based. In all, the combination of these substances have made up the environment that workers in this type of operation have had to endure in order to perform their duties.

For years, as a group, we suspected that a constant exposure to these types of chemicals was having some type of adverse effect on our health. However, until the Lung Cancer Mortality Study mentioned in Mr. Wright's statement, no solid evidence existed to support our suspicions.

Since agreeing to appear here today, I made an informal poll of a number of my fellow workers. I have found that at least 11 people in this one work area have contracted lung, throat or respiratory cancer in the recent past. Of these, 8 have died, and 3 have been treated and recovered or are recovering.

I am not here to tell you that American industry is responsible for this situation. Many industrial operations require use of dangerous and volatile chemicals. This is a fact of life.

I am saying that any law that will require the collection and analysis of information which would determine high-risk areas of work and as a result give early warnings to those employed in such areas and assist them in receiving prompt and effective monitoring and treatment would, I believe, become one of the most important pieces of legislation for American workers in this decade.

Again I would like to thank you for this opportunity to express my feelings and would be happy to answer any questions at the appropriate time.

[Information referred to above follows:]

United Steelworkers of America

DISTRICT 31
LOCAL UNION No. 1066

1221 EAST 37th AVENUE — GARY, INDIANA 46409
(219) 887-0591

JIMMY CROSS
VICE-PRESIDENT

ROBERT WATSON
RECORDING SECRETARY

CARY KRANZ
PRESIDENT

SAMUEL AMPELIOTIS
FINANCIAL SECRETARY

DON BONO
TREASURER

LIST FOR SENATE HEARING Feb. 24, 1987
WASHINGTON D.C.

1. Herman Gotti	Lung Cancer - Shot self when told was terminal.
2. Marcella Momon	Lung Cancer - Deceased
3. Jim Spencer	Lung Cancer - Deceased
4. Floyd Long	Lung Cancer - Deceased
5. Emil Lasco	Lung Cabcer - Deceased
6. James Champion	Lung Cancer - Deceased
7. Bill Fitzgearld	Lung Cancer & Emphysema - Died heart attack.
8. Bob Nelson	Throat Cancer - Deceased
9. Bill Brown	Throat Cancer - Deceased
10. Dave Turly	Throat Cancer - Successfully treated.
11. Harry Lamb	Throat Cancer - Successfully treated.

Senator METZENBAUM. Thank you, Mr. Watson.

Mr. Cafasso.

Mr. CAFASSO. My name is George Cafasso.

I am the Chairman of the Health and Safety Committee for Local Union 1557, Steelworkers of America. For the past 17 years, I have been employed at Clairton Works, Clairton, Pennsylvania.

Clairton Works is comprised of a coke-making operation and a coal chemical plant. The by-products operations produce coal tar, coke oven gas, and light oil. Coal tar is further distilled to produce coal tar, pitch and creosote. The light oil is also distilled to produce benzene, toluene, and xylene. Some of these products have been known to cause cancer and leukemia.

Clairton Works is a plant that once employed approximately 4,500 employees, but due to the recession in the basic steel industry, it now employs about 1,200 employees. My concern is not only for those 1,200 employees who are still working, but also for the 3,300 people who have left the work force, never realizing the hazards they were exposed to or that they were at risk of disease.

For that reason, as an employee representative, I firmly believe that this piece of legislation is so important in the work place today.

Thank you.

Senator METZENBAUM. Thank you.

Mr. Watson and Mr. Cafasso, you both are covered by the Hazard Communication Standard. Are you aware of that particular standard which is put out by regulation by the Department of Labor?

Mr. CAFASSO. Do you mean the "right to know"?

Senator METZENBAUM. Yes, so-called.

Mr. CAFASSO. Yes, I am aware of it.

Mr. WATSON. Yes.

Senator METZENBAUM. Does that standard give you the kind of information called for in this bill, and have you or any of your coworkers been told to go and see a doctor under that standard?

Mr. WATSON. I have worked for 23 years in the continuous pickling, and I have never been notified by anyone that I was at risk other than that you are dealing with hazardous chemicals, but not what the personal risk was to my health.

Personally, I have not had a chest x-ray in over ten years. However, after reading this study, I can guarantee you I certainly will have upon returning home.

Senator METZENBAUM. Mr. Cafasso.

Mr. CAFASSO. I worked in this plant for 17 years, and last year was the first time that I actually had a blood test to detect any benzene in my blood. The "right to know" or the Material Safety Data Sheets for the materials do not actually tell you what disease can be caused from these chemicals. They actually tell you what effect it has on your skin, on your throat, but actually does not tell you that it might create cancer or might create leukemia. It does not warn the employees to that effect.

Senator METZENBAUM. Do you feel it is inadequate to give you the kind of notification to which you believe you are entitled?

Mr. CAFASSO. Oh, yes, very inadequate, because they give you a book of about 2,000 pages and expect you to go and look for that particular substance, and when you find it, it does not give you the information that you are looking for.

Senator **Metzenbaum**. Do you think that you or your fellow employees can possibly comprehend the significance of the exposures that you are living with day-by-day by getting a 2,000-page book and being told to look up the agent?

Mr. **Cafasso**. No, not at all.

Senator **Metzenbaum**. Have you ever seen such a book, Mr. Watson?

Mr. **Watson**. I have never seen it.

Senator **Metzenbaum**. What do you think about the argument that we should not tell employees that they are at risk of cancer and should see a doctor because that might cause an increase in lawsuits against the employers?

Mr. **Watson**. I do not see how this legislation is going to change that. If I am at work and physically injured, I have that recourse now, or if I become sick by a fault of the company, I have that right currently, so I do not see how anything included in this legislation is going to change that one iota.

Senator **Metzenbaum**. Mr. Cafasso.

Mr. **Cafasso**. I do not see anything wrong with letting the employee be aware of what substances he is working with and what causes might come out of that exposure.

Senator **Metzenbaum**. Senator Matsunaga.

Senator **Matsunaga**. Thank you, Mr. Chairman. You asked all the questions I wanted to ask.

Senator **Metzenbaum**. Thank you very much.

I believe some members of the Committee may have questions—as a matter of fact, the Chair himself has some additional questions—but by reason of the hour and by reason of the Chair's very strong feeling that it is imperative that we hear from the next four witnesses, I am going to say thanks to each of you for being with us today. Your testimony has been very helpful.

Mr. **Samuel**. Thank you very much.

Senator **Metzenbaum**. Our last panel includes Mr. Leslie Cheek, Senior Vice President of Federal Affairs, Crum and Forster Insurance Companies; Mr. Robert E. Finnigan, American Electronics Association; Mr. Robert Clark, National Tooling and Machining Association; and Mr. Tom Evans, National Association of Manufacturers.

I think you have all heard the Chair's suggestion that everybody confine themselves to five minutes, and you get a certificate of award if you take something less than that.

Mr. Cheek, we will be very happy to hear from you first, sir.

STATEMENT OF LESLIE CHEEK, SENIOR VICE PRESIDENT OF FEDERAL AFFAIRS, CRUM & FORSTER INSURANCE CO'S.; ROBERT E. FINNIGAN, CHAIRMAN, ENVIRONMENTAL AND OCCUPATIONAL HEALTH OPERATING COMMITTEE, AMERICAN ELECTRONICS ASSOCIATION; ROBERT CLARK, NATIONAL TOOLING AND MACHINING ASSOCIATION; AND TOM EVANS, NATIONAL ASSOCIATION OF MANUFACTURERS

Mr. **Cheek**. Thank you, Senator. Good morning.

The companies I represent are the nation's second-ranked writers of general liability insurance and among its largest workers' compensation carriers. We very much appreciate this opportunity to present our views on legislation which, if not properly structured and limited, we believe could have a catastrophic impact on the costs of our two largest lines of business.

We would like to begin by complimenting you, Mr. Chairman, for your decision to hold this hearing and for your obvious willingness to entertain constructive suggestions for further refinements in S. 79, which is itself a significant improvement over S. 2050 of the last Congress.

Our comments on your bill spring from two central principles.

The first is that employees should be notified that they are at risk of disease only when it is certain that they have been exposed to an occupational health hazard.

The second is that a disease notification and prevention program should neither serve as the basis for establishing the liability of an employer or a product manufacturer for permitting or creating an occupational health hazard, nor have any bearing on claims under existing law for harm arising out of an occupational health hazard.

In keeping with the first principle, we recommend first that substances, agents and processes found in the workplace be divided into two categories—those known, on the basis of clinical and epidemiological studies, to be capable of causing specific acute harms, illnesses or diseases; and, on the other hand, those for which there is evidence, from properly conducted animal and laboratory studies, suggesting that human exposure to them could significantly increase the risk of these same harms, illnesses or diseases.

Secondly, we would recommend that those employees known to be at risk of harm be so notified, and that those potentially at risk be subjected to further clinical and epidemiological study, at the expense of the employers who last harmfully exposed them to the suspected hazard, to confirm or deny the possibility of an occupational health hazard suggested by the animal or laboratory data.

Without these distinctions between known and potential hazards and different treatment of employees exposed to them, it is our judgment that this bill will result in needless notification of thousands of workers who are not at risk of occupational disease. Both the animal bioassay and tissue culture studies that the bill now permits to serve as the bases of determination that health hazards exist have inherent shortcomings that result invariably in overestimation of human risk and occasionally in indications of human toxicity that do not prove out in clinical and epidemiological studies.

Moreover, given the continuing controversy over whether animal or short-term studies can serve as surrogates for human experience, we believe it would be prudent to use these studies only as screening devices, if you will, for the identification of substances that are mutagenic in animals and therefore might be carcinogenic in humans, but not as the bases for conclusions that they are in fact carcinogenic in humans.

In keeping with our second principle, the "walling off" problem, we recommend that every step possible be taken to minimize the potential impact of the bill's program on the liability of employers for workers' compensation or tort claims by employees exposed to occupational health hazards and on the product liability of manufacturers of substances found to constitute occupational health hazards to either their own employees or the employees of others.

Subsection 10(g) of the bill makes a laudable attempt to do just this, to wall off the notification process from the adjudicatory process. But in our judgment, the section in its current form does not sufficiently mitigate the potentially catastrophic effect of this well-intentioned legislation on the workers' compensation and tort liability of any employer or manufacturer who uses or makes hazardous substances.

We have a number of other substantive concerns about the legislation, and these are addressed in some detail in our submission for the hearing record.

We would like to close by recognizing the long-term cost-saving implications of this bill, particularly its potential for reducing disease incidence through loss prevention efforts stimulated by its enactment and for reducing disease severity through early detection and timely treatment.

But in the same breath, we must plead with you, Mr. Chairman, to recognize through appropriate amendments that a notification program without sufficient safeguards against its scientific abuse and legal exploitation will generate short-term liability costs so huge as to dwarf its potential long-term value.

We thank you again for this opportunity to appear before you.

Senator METZENBAUM. Thank you, Mr. Cheek. I know we have been working with you, and we are prepared to continue working with you.

Mr. CHEEK. Thank you. I have enjoyed that already, Senator, and am looking forward to it myself.

Senator METZENBAUM. Thank you.

[The prepared statement of Mr. Cheek follows:]

Testimony of the
Crum & Forster Insurance Companies
Submitted for the Record of the
Subcommittee on Labor
Committee on Labor and Human Resources
United States Senate
at its Hearing on
S. 79, the High Risk Occupational Disease
Notification and Prevention Act of 1987

Washington, D.C.
February 24, 1987

Mr. Chairman and Members of the Subcommittee:

The Crum & Forster Insurance Companies are the Nation's second-ranked writers of general liability insurance and among its largest workers' compensation carriers. We are deeply concerned about the potential impact of S. 79 on the costs of the two lines of insurance that, in 1986, generated more than half of our $3.2 billion in premium.

S. 79 proposes a system for the notification and medical monitoring of employees found to be at increased risk of harm, illness, or disease as a result of their exposure to an "occupational health hazard." The bill creates a Risk Assessment Board ("the Board") which is empowered, with minimal procedural restrictions, to determine the existence of an occupational health hazard, the extent of the employee population exposed to it, and the members of the population who are to be notified of their increased risk of disease, on the basis of but a single ill-defined "study" it finds demonstrative of a significantly increased risk of a particular acute harm, chronic illness, or long-latency disease.

The Chairman of this Subcommittee has clearly signaled in this new legislation a willingness to consider major changes in his approach to occupational disease notification.

Gone is the infamous 30 percent increased risk "trigger" for notification in an earlier bill, S. 2050 of the 99th Congress. Added are some procedural safeguards in the process for selecting groups to be notified. Improved are provisions for "walling off" the notification of populations at increased risk from the adjudication of claims arising out of exposure to occupational health hazards.

The thrust and extent of the improvements in S. 79 encourage us to believe that there is at least the possibility of crafting additional refinements to the legislation that could produce a notification program that is consistent with recognized scientific principles and fair to both employers and employees.

But, notwithstanding the changes already made, the bill is, in our judgment, still significantly flawed. Without substantial amendment, it poses the risk of creating short-term costs that could subvert its potential long-term value.

Our comments on S. 79 spring from two central principles: the first is that employees should be notified that they are at risk of disease only when it is certain that they have been exposed to an occupational health hazard; the second is that a disease notification and prevention program should neither serve as the basis for establishing the liability of an employer or a product manufacturer for permitting or creating an occupational health hazard, nor have any bearing on claims under existing law for harm arising out of an occupational health hazard.

In keeping with the first principle, we recommend first that substances, agents, and processes found in the workplace be divided into two categories -- those known, on the basis of clinical and epidemiological studies, to be capable of causing specific acute harms, chronic illnesses, or long-latency diseases in human beings; and those for which there is evidence, from properly-conducted animal and laboratory studies, suggesting that human exposure to them could significantly increase the risk of these harms, illnesses, or diseases.

Secondly, we recommend that those employees known to be at risk of harm be so notified, and that those potentially at risk be subjected to clinical and epidemiological study, at the expense of the employers who last injuriously exposed them to the suspected hazard, to confirm or deny the possibility of an occupational health hazard suggested by animal or laboratory data.

Without these distinctions between known and potential hazards, and different treatment of employees exposed to them, it is our judgment that the bill will result in needless notification of thousands of workers who are not at risk of occupational disease. Both the animal bioassay and tissue culture studies that the bill now permits to serve as the bases of determinations that health hazards exist have inherent shortcomings that result invariably in overestimation of human risk and occasionally in indications of human toxicity that don't prove out in clinical and epidemiological studies.

Moreover, given the continuing controversy over whether animal or short-term studies can serve as surrogates for human experience, we believe it would be prudent to use these studies only as screening devices for the identification of substances that are mutagenic in animals and, therefore, *might be* carcinogenic in humans, not as the bases for conclusions that they *are*.

In keeping with our second principle, we recommend that every step possible be taken to minimize the potential impact of the bill's program on the liability of employers for workers' compensation or tort claims by employees exposed to occupational health hazards and on the product liability of manufacturers of substances found to constitute occupational health hazards to either their own or others' employees.

Subsection 10(g) of the bill makes a laudable attempt to "wall off" the notification process from the adjudicatory process, but, in our judgment, does not sufficiently mitigate the potentially catastrophic effect of this well-intentioned legislation on the workers' compensation and tort liability of any employer or manufacturer who uses or makes hazardous substances.

We also believe that the bill's procedures for making crucial substantive determinations are seriously flawed.

In its introduced form, S. 79 gives the Board limited but virtually unchallengeable discretion in the determinations of the existence of occupational health hazards and the size of populations at risk.

The Board itself is limited to a review of "studies," and must determine, from this review alone, the existence of the hazard, the size of the population at risk, and the form of notification. No consideration is required, and perhaps none was intended, of, for example, how a substance, agent, or process is used in industry; what safeguards are provided to reduce or eliminate employee exposures; or whether, given these facts, the studies are even relevant to employee working conditions.

And judicial review of these crucial determinations is to be based only "on the hearing record," not on the nature of the data underlying the "determinations" that are subject to the hearing process. Moreover, subsection 5(g)(3) so circumscribes the scope of judicial review as to prohibit any challenge to the Board's determinations based on either insubstantiality of the evidence in the record or inconsistency with the facts. This subsection is, in our judgment, utterly indefensible from the standpoint of procedural due process of law.

This procedural unfairness is compounded by the extremely short time frames within which major decisions must be made by all parties to the determination process. These deadlines have "railroading" written all over them, and are offensive to the complexity of the issues that will be involved in these determinations.

The final insult to due process of law in the introduced bill is subsection 5(g)(4), which renders meaningless any court decision adverse to the Secretary's determination, by providing that the "commencement of (judicial review) proceedings...shall not operate as a stay of the requirement on the Secretary to notify employees unless the court specifically orders a stay based on a determination by the court that the complaining party is highly likely to succeed on the merits." This standard for the issuance of a stay is to be found nowhere in Federal statutes or jurisprudence, and ignores the Administrative Procedure Act's direction that courts "issue all necessary and appropriate process to postpone the effective date of an agency action" in order "to prevent irreparable injury" and to "preserve status or rights pending conclusion of the review proceedings." (See 5 U.S.C. 705.)

The procedural aspects of the bill are vitally important if its notification process is, as section 4(b)(2) suggests, to be "based on the best available scientific evidence." Accordingly, sections 4(c) and 5(g) should be abandoned, and the Board should be required to comply with the Administrative Procedure Act.

In addition, we believe that each of the key determinations to be made under section 4 should be regarded as a separate final agency action. We think this revision is crucial, since the first determination -- the existence of an occupational health hazard -- is essential to the other two -- the identification of populations at risk of disease and the designation of individuals within those populations to be notified.

We recognize that these procedural revisions will lengthen the time it takes the Board to make its determinations, but we believe these determinations will be sounder for being subject to the fullest scope of public review and challenge.

In addition to these broad comments, we offer the following detailed critique of other aspects of the bill that we believe must be improved if the bill is to be scientifically sound, fair to both employers and employees, and minimally disruptive of current workers' compensation and tort law.

DEFINITIONAL PROBLEMS

The term "occupational health hazard" is so broadly defined as to sweep in any "chemical, physical, or biological agent, or (any) industrial or commercial process" that could conceivably produce "acute or chronic health effects in exposed employees."

Moreover, it is worded in such a fashion as to make "one study conducted in accordance with established scientific principles" determinative of whether a particular physical or biological agent, or industrial or commercial process is to be deemed an "occupational health hazard." The definition does not specify whether these studies are to be epidemiological or clinical studies, or merely laboratory tests conducted with animals or tissue cultures. Nor does it give real world studies any greater weight than speculative experiments. Worst of all, it pays no attention to the crucial variables in any meaningful definition of an occupational health hazard -- concentration and duration of exposure.

The definition is further flawed by the vagueness of its requirement that a study -- any study -- provide "statistically significant evidence" of potential health effects among exposed employees. What does "statistically significant" mean? And who is to decide what it means? Will a laboratory study of the type that the Consumer Product Safety Commission relied upon to ban the use of formaldehyde be deemed as "statistically significant" as the epidemiologically proven link between asbestos exposure and asbestosis?

Most alarming, however, is the inversion of reality that the definition accomplishes in tandem with the definition of "population at risk of disease." The latter definition explicitly says that if an employee population is exposed "at intensities or durations comparable to (those used in) at least one" of the studies referred to above, that population is "at risk of disease." In other words, if a bunch of six-ounce mice contract disease X when exposed to certain amounts of chemical Y over a certain period of time, then all 160-pound humans exposed to any more than this amount for any longer period are automatically a "population at risk of disease." This is ludicrous on its face, and cannot rationally serve as the basis of notification policy.

These fundamental problems can be addressed by revising the definition of "occupational health hazard" to (1) limit the studies that may be relied upon to clinical or epidemiological studies; (2) import concepts of intensity and duration of exposure into the process of determining the existence of a hazard; and (3) require that employee exposures in the specified concentrations and durations be known to be capable of causing the disease at issue.

All of these changes are crucial to an acceptable notification program. Without them, virtually every chemical in industrial use will be labeled an "occupational health hazard" on the basis of dubious laboratory experiments alone.

First, the studies upon which a finding of the existence of an "occupational health hazard" can be made must be limited to those involving human experience, and cannot include animal or laboratory studies.

If animal studies were to serve as surrogates for human experience in the formulation of notification policy, the Government would end up notifying vastly more workers than are truly at risk, because the most widely used model for these tests -- the linear extrapolation from the risk observed at high doses to that supposed at low doses -- invariably errs on the side of overpredicting the true risk.

Moreover, controversy still rages over whether rats and mice can be regarded as "little men," or whether there are important physiological differences in the way rodents and higher primates handle carcinogens. This uncertainty involves not only the *qualitative* issue of whether a given substance is or isn't a human carcinogen, but the equally vital *quantitative* issue of whether the degree of risk to humans can be assessed from the degree of risk seen in rodents.

Moreover, there are already several instances in which epidemiology has been unable to confirm cancer risks to humans suggested by animal tests (e.g., saccharin, hair dyes, DDT).

Finally, and most significant, animal studies, through manipulation of dosages, have already "proved" that hundreds of chemicals, including table sugar, pepper, eggs, and Vitamin D, are carcinogenic in animals. Would it be rational to assume, on the basis of such tests, that these substances imperil the health of human workers who make, use, or ingest them?

While short-term tests -- bacteria and mammalian cells in tissue culture (e.g., the Ames test) -- correlate highly with the results of animal bioassays and produce fewer "false positives," they nevertheless miss such hormonally active carcinogens as DES and, particularly important in the workplace context, carcinogens that act by means of chronic irritation (like asbestos) and some chlorinated hydrocarbons (Dioxin, for example) that are proven carcinogens in animal tests or humans.

Animal and tissue culture tests would be undeniably useful in preliminary screening of large numbers of chemicals to identify the exceptionally mutagenic (and, hence, presumptively carcinogenic) ones, but they should serve only as the basis for establishing priorities for human clinical and epidemiological studies, not as the basis for a finding that the suspect chemicals constitute "occupational health hazards."

Second, concepts of intensity (or concentration) and duration of exposure must be imported into the definition of "occupational health hazard," in that substances normally thought to be relatively benign -- oxygen, alcohol, and water, for example -- can be toxic in sufficient quantities and over short periods of time, and substances considered highly toxic are quite harmless in small amounts over long periods of time. The most obvious examples are the thousands of naturally-occurring chemicals found in a variety of foods -- mycotoxins, hydrazines, flavonoids, tannins, etc.

The concepts of concentration and duration of exposure in the definition of "occupational health hazard" are essential, too, if the notification process is to be driven by "real world" experience, rather than by speculative statistical extrapolations. As noted above, all of the experimental surrogates for human experience have inherent weaknesses that make them inappropriate as bases for conclusions that the substances involved are "occupational health hazards."

Third, the definition of "occupational health hazard" should require that the clinical and epidemiological studies used as the basis of the Board's findings show that the substance, agent, or process is capable of causing the disease at issue among the exposed workers involved.

POTENTIAL DUPLICATION OF EFFORT

Given the enormous universe of chemicals (60,000) in industrial use, it would make sense for the legislation not only to establish priorities for identifying occupational health hazards and populations at risk of disease, but also to avoid duplication of similar efforts under way at the Occupational Safety and Health Administration (OSHA) in connection with the hazard communication standard (29 C.F.R. 1910.1200).

Thus, while there is some logic in having the Board created by Section 4 of the legislation staffed by career or commissioned Public Health Service (PHS) employees, there is no reason why the Board cannot be detailed to or report to the Secretary of Labor through the Assistant Secretary for Health of the Health and Human Services Department. Such a reporting arrangement would assure both the independence of the Board and coordination with OSHA to avoid duplicative research.

Indeed, were the hazard communication standard to be extended to cover all employers, as it might well be, it would make sense to fold the new notification program into that already in place, with whatever refinements are needed.

IMPRECISION OF CRITERIA FOR HAZARD RANKING

Subsection 4(b)(2) of the bill quite properly attempts to outline the factors that the Board should consider in identifying populations at risk, but, like the definition of "occupational health hazard," does not give sufficiently clear priority to those hazards that have been identified through epidemiological or clinical observations of human populations.

In our judgment, subsection 4(b)(2) should be divided into two subsections, the first captioned as "Identification of Occupational Health Hazards," and the second as "Identification of Potential Occupational Health Hazards." Both subsections should establish priorities for identifying these hazards. Here, as in the definition of such hazards, the key for differentiating among actual and potential hazards should be the availability of "real world" evidence of health hazards versus animal and laboratory studies merely suggestive of such hazards.

In both subsections, the highest priority should be given to those actual or potential hazards which pose the greatest risk of disease to the largest number of exposed workers, and to the identification of those industrial classifications and job categories posing the greatest risk to employees.

IMPRECISION OF CRITERIA FOR POPULATION IDENTIFICATION

The criteria in the existing subsection 4(b)(3) could then be moved into yet another subsection detailing the criteria for establishing priorities for notification of members of identified populations at risk of disease. Here, we are not certain that "populations likely to benefit from medical surveillance or health counseling" should necessarily be the first to be notified. This criterion appears to contemplate giving secondary consideration to notifying workers who may be at far higher risk of disease, but who may not necessarily be able to benefit from medical surveillance and health counseling.

Indeed, we would recommend that the priorities for notification track those for identifying health hazards and populations at risk, which are clearly ranked by the severity of the hazard and the degree of increased risk. Notification priorities should not "write off" workers for whom relevant disease latency periods may be nearing their end solely because they may not be able to benefit as much from disease prevention efforts as other exposed worker populations.

ARBITRARY NOTIFICATION QUOTAS

Finally, we are distressed by subsection 4(b)(3)(C), which directs the Board to "notify or coordinate notification of not less than 100,000 employees per year." Our distress relates not to the goal of notifying as many workers as should be notified as early as possible, but rather to the establishment of what appear to arbitrary quotas.

We are concerned that, out of the necessity of meeting artificial objectives, the Board may be forced into slipshod science and hasty decision-making that might result in over-notification or notification of populations for whom the evidence of increased risk is questionable. We would recommend restating the subsection to require the Board to notify as many workers as is reasonably possible within the limitations of its resources and of the criteria set forth in the statute for assuring procedural due process of law.

The danger of establishing numerical goals for a program based on medical and scientific data is vividly illustrated by the history of the Black Lung Benefits Act. As originally enacted in 1969, the Act contained a superb definition of complicated coalworkers' pneumoconiosis, a disease whose etiology and symptoms were well understood in the medical community. The Social Security Administration administered the Act perfectly, awarding benefits only to those miners suffering from complicated coalworkers' pneumoconiosis. But the sponsors of the Act wanted to compensate more miners, and the original law was progressively watered down, first in 1972 and again in 1977, to the point that, before Congress reacted to its own excesses in 1981, a person with 15 years of "mining employment" and any respiratory ailment whatsoever was irrebutably presumed to be totally disabled by coalworkers' pneumoconiosis! The result: more persons are receiving black lung benefits today than ever worked in underground coal mines in the entire history of this country.

INSUFFICIENTLY FLEXIBLE NOTIFICATION PROCEDURES

On the issue of how employees in populations at risk of disease are to be notified, S. 79's subsections 6(b)(1) and (2)(A) make an encouraging move toward permitting private and public employers to carry out the Secretary's notification obligations to these employers' current and former employees.

But subsection 6(b)(2)(B) undercuts the thrust of this move by foreclosing contracts with employers willing to relieve the Secretary of his or her obligations, and by flatly denying them access to Federal records that might help them carry out this function. Since employers are the most likely source of employment and exposure history, current addresses and other employee data, it strikes us as odd that the bill seems to go out of its way to preclude contractual arrangements and data exchanges that would save the Government countless manhours and numberless dollars.

We suggest that section 6(b)(2)(B) be rephrased to simply preclude employers from profiting from their contractual arrangements in carrying out the notification, and to permit the Government to provide employers with the data that they need to reach former employees. Without these changes, most employers would likely "let Uncle Sam do it," at vastly greater cost to the taxpayers. Since Federal dollars will be involved whether Uncle Sam or employers do the notification, why not encourage, rather than discourage, the cheaper and faster alternative?

LIABILITY IMPLICATIONS OF NOTIFICATION

We come finally to perhaps the most difficult problem posed by S. 79 -- the potential impact of the notification program on the liability of employers for workers' compensation or tort claims by employees exposed to occupational health hazards and on the product liability of manufacturers of substances found to constitute occupational health hazards to either their own or others' employees.

We do not believe that subsection 10(g) does enough to "wall off" the notification process from the adjudicatory process, nor are we convinced that any set or words could mitigate the potentially catastrophic effect of this well-intentioned legislation on the workers' compensation and tort liability of any employer or manufacturer who uses or makes hazardous substances.

First, notwithstanding subsection 10(g)'s clear intent to foreclose such claims, we are very concerned that the mere act of notifying worker populations that they are at high risk of contracting dread diseases will generate workers' compensation claims against their employers. We foresee these claims falling into two categories: (a) "stress" claims from workers in the notified populations; and (b) medical and indemnity claims from workers who have the disease specified in the notification.

Our concerns about the first category of claims are founded in the fact that allegations of work-related mental and/or physical stress are the fastest-growing class of workers' compensation claims today, even in the absence of a national notification program. It is inconceivable that notification of the sort proposed in the Act would not produce stress in every member of a notified population. How many of these workers would be disabled by this stress is a matter of conjecture, but we believe that the notification itself will stimulate workers' compensation stress claims, unless explicit safeguards against such claims are built into subsection 10(g).

Our concerns about the second category of workers' compensation claims relate to the difficult ethical and legal issues posed by a notification program founded, perhaps entirely, on biological inferences drawn from statistical analyses. The basis for any finding of "increased risk" of disease among exposed workplace populations is the background prevalence of that disease in the non-exposed general population. Under current circumstances, neither exposed workers nor their employers know which cases of a particular disease arose from workplace exposure and which would have occurred regardless of that exposure.

As a practical matter, we believe that the mere fact of notification will trigger findings that all notified workers who have or subsequently contract a disease have contracted it as a result of the workplace exposure. Indeed, legislation (H.R. 3090) introduced in the 99th Congress would have compelled such an outcome.

Notwithstanding subsection 10(g)'s valiant effort to prevent such outcomes, we believe that public records of notification would be used by claimants with the specified disease to buttress their workers' compensation claims that their harm is occupationally-derived, notwithstanding the statistical certainty that many, if not most, of such cases will not be occupationally-related, unless explicit safeguards against such misuse of information about the notification process are built into subsection 10(g).

Our concerns about these two categories of workers' compensation claims could be more fully addressed by providing, in subsection 10(g), that no information about notification or any other action or omission pursuant to the Act may be introduced, either directly or indirectly, in any proceeding under any workers' compensation law. If the program is truly intended only to prevent harm, then any information about its operation should be excluded from the process of determining whether particular workers' disease is occupationally-related.

Second, we are concerned that the notification program could provide notified workers with the basis for new legal detours around their employers' immunity from employee tort suits under workers' compensation laws. We foresee, based on a 1979 NIOSH notification experiment in Georgia that generated $335 million in lawsuits among 800 notified workers (see H. Rep. 99-691, 99th Cong., 2d sess., at 32-33), new assaults on employer tort immunity by notified workers alleging that their employers' actions in exposing them to the suspect substance or their employers' failure to earlier notify them of their increased risk constituted "intentional torts." In some jurisdictions, "intentional torts" are an exception to the general tort immunity of employers under workers' compensation laws.

Here again, we believe our concerns could be more fully addressed through language in subsection 10(g) explicitly precluding tort actions against employers by their employees (or by the employees' representatives) based on any act or omission governed by the Act. It would also be necessary to provide here, too, that no information about notification or any other action or omission pursuant to the Act may be introduced, either directly or indirectly, in any tort action arising out of workplace exposure to a hazardous substance.

Third, we are concerned that the manufacturers of chemicals or other products found to constitute occupational health hazards face a very real threat of individual and class product liability actions by members of employee populations found to be at increased risk as a result of these hazards. We believe the Act should be amended to explicitly preclude any such actions unless and until (1) the employees have objectively verifiable and medically diagnosed physiological symptoms of the disease or diseases that were the subject of the notice; and (2) the employees' workers' compensation claims against their employers have been finally adjudicated. In addition, the amount of any workers' compensation award should be deducted from any subsequent product liability judgment or settlement, and workers' compensation subrogation liens and actions of contribution or indemnity outlawed.

Fourth, we are convinced that several provisions of the bill will have the practical, if unintended, effect of undercutting the intent of subsection 10(g) to keep any information about the notification process out of claims adjudication procedures.

For example, subsection 5(d) plainly contemplates wide publicity about "any risk subject to notification under this section and its associated disease." This obviously public information could easily be used to circumvent subsection 10(g)'s clear intent to keep out of evidence information about "the notification of an employee" or the fact that the employee "is in a population at risk." Subsection 10(g) should, we believe, be amended to explicitly exclude the direct or indirect evidentiary use of any information published pursuant to subsection 5(d).

Similar prohibitions should be included against the discovery for use in any workers' compensation case or any litigation of any studies, tests, or other materials made part of the record in any of the Board's proceedings. We see no merit in requiring the taxpayers to fund the costs of discovery for workers' compensation claimants' attorneys or for plaintiffs' attorneys in toxic tort or product liability cases.

Senator METZENBAUM. Mr. Finnigan, representing the American Electronics Association. We are happy to have you with us this morning.

Mr. FINNIGAN. Thank you very much, Senator.

Mr. Chairman, members of the Subcommittee, my name is Bob Finnigan. I am founder, Vice Chairman and Senior Vice President of the Finnigan Corporation. We are located in San Jose, California.

I am testifying before you this morning on behalf of the American Electronics Association. It is the largest trade association in the electronics industry, with approximately 3,000 member companies.

I am a member of AEA's Environmental and Occupational Health Committee, and in fact, I was previous Chairman of this for several years.

Mr. Chairman, I have prepared detailed testimony that I have provided to your staff and which I would like to submit for the record.

Senator METZENBAUM. Without objection, your entire statement will be included in the record. The same is applicable to all other members of the panel.

Mr. FINNIGAN. Thank you, sir.

Rather than review that testimony in detail this morning, I would like to limit my time here to make a few key points.

At the outset, I would like to emphasize that AEA endorses the principle that workers have a right to obtain complete disclosure about known occupational health hazards. It is for this reason that AEA supports the "right to know" concept.

Similarly, our Association also supports the notion that workers found to have a high risk of contracting a particular disease because of workplace exposures should be informed of that fact. This is a goal of S. 79, and we endorse that goal.

It is also AEA's opinion that S. 79 represents a marked improvement over last year's Senate bill, and we are appreciative of the efforts that have been made to incorporate some of the concerns of the electronics community.

Despite our support for this effort, we believe that further changes are in order. In particular, AEA strongly urges that the legislation be amended to ensure the scientific integrity of the notification process. The initial determination that a particular group of workers has a high risk of contracting a certain disease should be made only on the basis of documented scientific data. Likewise, the determination that such a high risk was caused by exposures that occurred in the workplace and not by other exposures requires careful scientific analysis. A failure to adhere closely to widely accepted scientific principles in identifying affected populations will result in unfairness to all parties and a fundamental breakdown in the notification process.

If, for example, workers receive notice that they are in special danger of contracting a particular disease, when in fact there is little or no scientific basis for such a determination, both workers and employers are seriously disserved. In such cases, workers are subject to baseless anxieties, and employers and the government are subjected to substantial and unnecessary notification-related costs and are exposed to enormous potential liability.

To help bolster the scientific basis of S. 79, AEA offers several suggestions. First, we recommend that S. 79's reference to the acceptability of one study as the basis for worker notification should be dropped. This is no numbers game. Rather than specify the number of studies needed, AEA recommends that the identification of an occupational health hazard be based on sound medical and epidemiological principles, including consistency, specificity, and strength of association, dose response relationship, biological plausibility, temporal relationship and statistical significance.

Second, AEA recommends that worker notifications be tailored as closely as possible to actual exposure experience, with worker groups identified with reference to specific exposure experiences that are shared in common.

Broadly-defined categories of employees that include a wide range of types and intensities of exposure, such as workers in the chemical industry, cannot be used for notification purposes.

Third, consistent with AEA's strong view that S. 79's worker notification scheme should be driven by science, AEA objects to the bill's requirement that at least 100,000 employees be notified per year. If the notification system is to have the scientific integrity that is needed to make it fair and effective, it is counterproductive to mandate that a particular number of notifications occur in a particular year.

Senator METZENBAUM. Could you wind up, Mr. Finnigan?

Mr. FINNIGAN. Yes. I am about to finish, Senator.

Senator METZENBAUM. Thank you.

Mr. FINNIGAN. Fourth, AEA recommends that the proposed Risk Assessment Board should be expanded in size to accommodate a biostatistician and physicians who specialize in occupational medicine. These additions would help ensure the integrity of the scientific determinations entrusted to the Board. As a further check on the Board's work, we strongly recommend that a science advisory board be created to review the determination of populations at risk identified by the Risk Assessment Board and to advise the Secretary concerning their findings and recommendations.

We have other, additional improvements, and these points have been developed in our written testimony, and they address the important questions of employer liability, the composition and procedure of the Risk Assessment Board, and the reassignment of exposed workers.

In conclusion, AEA appreciates the opportunity to testify on S. 79, a bill that promotes a goal that AEA fully endorses. We hope that our concerns offer constructive assistance, and we really look forward to working with the Committee on this very important legislation.

Thank you.

Senator METZENBAUM. Thank you very much, Mr. Finnigan. We very much appreciate the fact that your organization, the American Electronics Association, supports the overall thrust of the legislation. You have been helpful. We have been working with you, and we look forward to working further with you to see if we can fashion a bill that meets your organization's objectives and concerns.

[The prepared statement of Mr. Finnigan follows:]

Statement of Robert E. Finnigan
Vice Chairman and Senior Vice President
Finnigan Corporation
San Jose, California

before the

U.S. Senate
Subcommittee on Labor
Committee on Labor & Human Resources
Washington, D.C.
February 24, 1987

Introduction

Mr. Chairman, members of the subcommittee: My name is Robert E. Finnigan. I am Vice Chairman and Senior Vice President of the Finnigan Corporation in San Jose, California. The Finnigan Corporation is a high-technology instrument company that specializes in the manufacture of sophisticated analytical instruments and is the major manufacturer of mass spectrometers and gas chromatograph/mass spectrometer (GC/MS) combination systems.

Description of AEA

I am testifying before you this morning on behalf of the American Electronics Association. I am a member and past Chairman of the Environmental and Occupational Health Operating Committee of AEA.

AEA is the largest trade association in this nation's largest manufacturing industry. AEA represents more than 3,000 member companies nationwide, and also more than 450 financial, legal, and accounting organizations which participate as AEA associate members. AEA encompasses all segments of the

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electronics industry, including manufacturers and suppliers of computers and peripherals, semiconductors and other components, defense systems and products, telecommunications equipment, instruments, software, research, and office systems. The AEA membership includes companies of all sizes, from "start-ups" to the largest companies in the industry. The largest number of AEA members -- more than 70 percent -- are small companies employing fewer than 250 employees. Together, our companies account for 63 percent of the worldwide sales of the U.S.-based electronics industry.

The Importance of Notifying Workers of Occupational Hazards

Mr. Chairman, AEA concurs fully in S. 79's determination that "workers have a basic and fundamental right to know that they have been exposed to an occupational health hazard and are at risk of contracting an occupational disease." AEA endorses the principle that workers have a right to obtain complete disclosure about known occupational health hazards. It is for this reason that AEA supports the "right-to-know" concept. Based on this support for "right-to-know," AEA and member companies have assisted implementation of OSHA's new Hazard Communication Standard on the federal level, as well as state "right-to-know" initiatives. Similarly, AEA has supported and is assisting "community right-to-know" efforts including, for example, constructive disclosure of company activities to emergency response personnel.

In view of AEA's commitment to right-to-know, it should not be surprising that our association also supports the notion that workers found to have a high risk of contracting a particular disease because of workplace exposures should be informed of that fact. This is the goal of S. 79, and we endorse that goal.

It also is AEA's opinion that S. 79 represents a marked improvement over last year's Senate bill and we are appreciative of the efforts that have been made to incorporate some of the concerns of the electronics community. As further delineated below, however, further changes are still in order. In the spirit of continued cooperation with the Committee, AEA looks forward to working with Committee members to include necessary changes in the legislation. The result will be a federal law which best fulfills the objectives of S. 79.

The Importance of Establishing A Fair and Effective Worker Notification System That Is Based On Widely-Accepted Scientific Principles

Mr. Chairman, while AEA endorses the goal of S. 79, we also strongly believe that the legislation must be crafted to be fair and effective and firmly grounded in widely-accepted scientific principles. We wish to especially emphasize the scientific issues. The scientific integrity of the notification process is not an end that should be achieved for its own sake, but it is an important means to an end. Simply put, the scientific basis for notifying workers is a critical factor in achieving the goal of a fair and effective notification process. The initial determination that a particular group of workers has a high risk of contracting a certain disease, for example, should be made only on the basis of documented scientific data. Likewise, the determination that such a high risk was caused by exposures that occurred in the workplace, and not by other exposures, requires careful scientific analysis.

A failure to adhere closely to widely-accepted scientific principles in identifying affected populations will result in unfairness to all parties and a fundamental breakdown in the notification system. If, for example, workers receive notice that they are in special danger of contracting a particular disease when, in fact, there is little or no scientific basis for such a determination, both workers and employers are seriously disserved. In such cases, workers are subjected to baseless anxieties, and employers and the government are subjected to substantial and unnecessary notification-related costs and exposed to enormous potential liability.

S. 79 represents an improvement over last year's bill because it begins to integrate scientific principles into the legislation. The new definitions for "occupational health hazard" and "population at risk of disease," for example, acknowledge that the identification of a workplace hazard must be based on scientific data that passes muster under "established scientific principles," and that duration and intensity of exposure are critical factors in identifying affected worker populations.

Despite these improvements, AEA believes that the proposed legislation must include a number of key scientific and procedural elements fundamental to any fair and effective worker notification initiative. Several of these elements are discussed in greater detail below.

Identification of Occupational Health Hazards

One of the key elements of the worker notification concept is the linkage between a particular type of workplace exposure and the development in defined populations of a particular disease. Once such a link has been established, there is little question that affected workers should be informed. On the other hand, a notification process that is not based on a close linkage between an occupational exposure and contraction of a particular disease will create unjustified and counterproductive alarm in workers. It also will generate significant, unnecessary notification expenses for employers and the government, and unjustified follow-up medical costs and potential liability.

S. 79 recognizes the importance of the causal link between an occupational exposure and the contraction of a specific disease, but the bill does not include the safeguards needed to ensure that the link has been established through widely-accepted medical and epidemiological principles. Specifically, in defining an "occupational health hazard," S. 79

refers to workplace agents that cause acute or chronic health effects based on statistically significant evidence which is defined, in turn, as evidence that is "based on at least one study conducted in accordance with established scientific principles."

S. 79's reference to the availability of "one study" falls short of the type of scientific rigor that should be applied before a causal link is drawn between a workplace exposure and contraction of a disease. This is no numbers game: rather than specify the number of studies needed, AEA recommends that the identification of an "occupational health hazard" be based on sound medical and epidemiological principles, including consistency, specificity, and strength of association, dose-response relationship, biologic plausibility, temporal relationship and statistical significance. Adherence to these well-recognized scientific guidelines is needed to ensure the integrity of the critical first step of the notification process. Similarly, less weight must be given to animal studies, rather than human health studies, in accordance with accepted scientific principles.

Identification of Affected Worker Populations

Once a causal link has been drawn between a workplace exposure and the contraction of a certain disease, worker groups who have encountered equivalent exposures must be identified and notified. This process of identifying the appropriate workers is a delicate and all-important one. If notifications are sent to workers who have not had the types of exposure that are needed to contract disease, the notification process will becounterproductive. Workers' anxieties will be raised and employers will once again be exposed to significant potential liability.

S. 79 identifies affected worker populations by referencing populations that have been exposed to an occupational health hazard "at intensities or for durations comparable to [those included in] at least one study . . . ." This language takes an important first step by acknowledging that only those worker populations that have actually been exposed to a sufficient degree to an occupational health hazard should receive notice.

The integrity of the notification process depends on the tailoring of worker notifications as closely as possible to actual exposure experience. Broadly-defined categories of employees that include a wide range of types and intensities of exposure, such as "workers in the chemical industry," can not be used to notification purposes. Instead, worker groups must be identified with reference to specific exposure experiences that are shared in common. By defining exposure levels as precisely as possible, there will be some assurance that the appropriate workers receive notification. Mechanisms for determining when exposure at levels of concern has taken place should be carefully considered. In particular, when data exists on a plant-by-plant basis, it should be part of the process of defining the populations that are to receive notification.

Number of Workers Notified

Consistent with AEA's strong view that S. 79's worker notification scheme should be driven by science, AEA objects to the bill's arbitrary requirement that at least 100,000 employees be notified per year. If the notification system is to have the scientific integrity that is needed to make it fair and effective, it is counterproductive to mandate that a particular number of notifications occur in a particular year. Scientific considerations -- and not arbitrary quotas -- should provide the basis for worker notifications.

Congress can better ensure agency implementation of this legislation through effective and vigorous use of the oversight process. To assist that process, AEA recommends that the annual report to Congress required by section 11 include a detailed forecast of the Risk Assessment Board's proposed activities for the coming year.

Liability

As I already have explained, one of AEA's principal reasons for urging this Committee to base its worker notification scheme on firm scientific grounds is to limit the enormous potential liability that may face employers once workers are told that their workplace exposures may lead to the contraction of certain diseases. To the extent that a broad brush is used to identify worker populations that should be notified, and to the extent that notification is based on weak science, employers will face large out-of-pocket expenses associated with notification, monitoring, and other follow-up costs, as well as substantial liability for worker claims for additional compensation.

AEA urges that this Committee recognize this serious liability threat by carefully tailoring its notification requirements to ensure that notifications are made as precisely as possible to the affected worker groups. In addition, AEA requests that S. 79 be amended to clarify the apparent intent of Section 10(g), namely, that a worker's inclusion in a population at risk, receipt of a notification, and participation in medical evaluation and monitoring should not on their own be used as evidence in any claim for compensation, loss, or damage arising out of the hazardous occupational exposure. The group notification process cannot possibly evaluate individual exposures, and it should not be used for that purpose.

The Risk Assessment Board

AEA recommends also that certain changes be made in the structure and procedure of the proposed Risk Assessment Board. We believe that the Board should be expanded in size to accommodate a biostatistician and physicians who specialize in occupational medicine. These additions would help ensure the integrity of the scientific determinations entrusted to the Board.

As a further check on the Board's work, we recommend that a Science Advisory Board be created to review the determination of populations at risk identified by the Risk Assessment Board and to advise the Secretary concerning their findings and recommendations. Review by a Science Advisory Board is an important element of many current government health-related determinations, and the special assistance that can be given by such a Science Advisory Board should be utilized for worker notifications as well.

In addition, AEA believes that S. 79's placement of final authority for notification decisions solely in the hands of the Risk Assessment Board is an extraordinary and unwarranted departure from customary agency practice. We recommend, instead, that final notification decisions be made by the Secretary of Health and Human Services, based on the Board's recommendations, and with the benefit of additional public comment.

Additional Comments

AEA has a number of additional concerns with S. 79 as presently drafted. In particular, the bill allows personal physicians great latitude in removing notified workers from the workplace. This provisions can have immense implications for manufacturers, especially small manufacturers. We believe that this decision should be made jointly by employee and company physicians. If there is continued disagreement, an independent physician agreeable to both parties should be consulted.

AEA also is concerned about the short time periods provided in the bill for filing comments and for challenging decision of the Risk Assessment Board. In many areas of the country, Federal Registers are not available on a timely basis. It simply will not be possible to undertake the analysis required to assess notification decisions in the 30 and 45 day timeframes allowed in S. 79. AEA recommends that the time periods be extended to 90 days, consistent with provisions in other statutes.

Summary

AEA appreciates the opportunity to testify on S. 79, a bill that promotes a goal that AEA fully endorses. AEA believes that S. 79 includes a number substantial improvements over the legislation considered in the last Congress. Nonetheless, additional modifications should be made to S. 79. In particular, AEA recommends changes that will help ensure that the notification process is based on widely-accepted scientific principles. AEA hopes that its ideas will assist the Committee in its consideration of S. 79, and we look forward to working with the Committee on this important legislation.

Senator **Metzenbaum**. We will next hear from Mr. Clark, of the National Tooling and Machining Association. Mr. Clark is from my home State, Dayton, Ohio. It is my understanding we have also been working with the National Tooling and Machining Association and have held a number of meetings with them.

We are very happy to welcome you here this morning, Mr. Clark.

Mr. **Clark**. Thank you, Mr. Chairman and members of the Subcommittee.

On behalf of my 3,375 colleagues in the National Tooling and Machining Association, I want to thank you for the opportunity to appear here today with our observations on S. 79.

I am the Vice President of Administration of a tool and die company in Dayton, Ohio. Our company is one of approximately 1,000 tool and die companies in the State. We employ 600 people. I am also President of the Dayton Tooling and Machining Association, an association of 150 mostly small tool, die, mold and precision machining companies in the Dayton area.

As an employer, we never lack for challenges. Not only is the work that tool, die and precision machining companies do challenging, but we operate our companies in a fiercely competitive world economy. Over the last few years, we have witnessed a tremendous increase in foreign competition for the provision of tools, dies, and precision machining services from overseas and even the Third World countries.

This has placed my company and the other predominantly small tool and die shops in the United States in a tremendous cost-price squeeze. My industry is a highly-skilled labor and machine-intensive industry. Our employees have years of training provided by our companies and the association that I represent here today. We value those people very highly. Because of the mutual dependency which exists between us and our employees, we have a great concern with their health and welfare, and we already provide extensive medical/surgical benefits to cover the occurrence of any unforeseen medical difficulty.

Our total benefit costs add anywhere from 30 to 40 percent to our hourly wage costs. With wage rates as high as we pay, the combined effect makes it very hard to compete against foreign companies who pay no health benefits and whose wage rates are often a fraction of ours.

In fact, in 1986, the cost of providing health care for our employees was in excess of one dollar an hour, which exceeds the hourly labor cost in some countries selling products in the United States.

S. 79 on its face will only add to our costs, thereby putting us in a deeper competitive hole. What is true for us is, of course, true for all members of our association. I therefore respectfully request that this Subcommittee consider alternative funding mechanisms to pay for what we perceive as a very well-intentioned program.

The Subcommittee should also assure that clear and convincing evidence of a population at-risk is necessary prior to requiring any notification. Without a legally-defined, enforceable standard, the risk of false alarms and bureaucratic busy work will run high.

Mr. Chairman, when you met with several of my Ohio colleagues earlier this month and during last year's hearing, you indicated the intention that the bill not create any undue burden on employers. If the solvents, cutting oils and cleaning agents necessary to our manufacturing processes are found to be the cause of occupational disease, the costs of testing and treatment will ultimately be reflected in the costs of our products. Those costs could be direct or reflected in higher insurance or chemical costs as a result of testing, treatment or legal fees and settlements.

For that reason, it is important to fill in several important blanks in the attached chart to compute the impact in terms of added costs to the product and then, if that figure is significant, calculate the impact in terms of jobs lost by means of an econometric model.

Only when this figure is available would you have a measure of the downside risk and thus be in a position to decide how to proceed.

American industry is presently bleeding to death, not as a result of some single, lethal wound, but rather, due to hundreds of small wounds, each seemingly insignificant on its own. All these wounds were inflicted with good intentions and for the greater good of all involved, but the result is the same. We have lost thousands of jobs and will lose thousands more, unless the bleeding stops. But the healing process cannot begin until the wounding stops. That is why we are here today.

Mr. Chairman, I have attached to my testimony a two-page paper of suggested technical corrections to the proposed Act. I have focused on the cost competitive issue because I think it is the most fundamental one.

I would be very happy to respond to you and your Committee's questions.

Thank you.

Senator METZENBAUM. Thank you very much, Mr. Clark. We appreciate the opportunity to work with your organization. I would make one observation in connection with your cost figures—and indeed I did meet with some of the tool and die makers, and at that point, I indicated my concern that we just not find ways to add to the costs of employers. I might say to you that the notification costs under our bill provide that the government will pay those costs, and it is included in our $25 million figure, and the only cost to the employer would be if the employer opts to make the notification himself or herself. So that is one part of the cost.

I might also make the observation that there very well could be a major cost, if an employee comes down with an occupational illness, is absent for a number of weeks or months, and the equipment remains idle by reason of that fact; I think that is a countervailing force. These are things we are prepared to talk with you about.

[The prepared statement of Mr. Clark follows:]

National Tooling & Machining Association

NTMA
PRECISION

BEFORE THE SUBCOMMITTEE ON LABOR

U.S. SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

February 24, 1987

TESTIMONY OF

ROBERT CLARK, VICE PRESIDENT OF ADMINISTRATION

DAYTON PROGRESS CORPORATION

DAYTON, OHIO

ON BEHALF OF THE
NATIONAL TOOLING AND MACHINING ASSOCIATION

9300 Livingston Road • Ft. Washington, Maryland 20744 • (301) 248-6200

CHAIRMAN METZENBAUM, MEMBERS OF THE SUBCOMMITTEE:

ON BEHALF OF MY 3,375 COLLEAGUES IN THE NATIONAL TOOLING AND MACHINING ASSOCIATION, I WANT TO THANK YOU FOR THE OPPORTUNITY TO APPEAR HERE TODAY WITH OUR OBSERVATIONS ON S.79.

I AM THE VICE PRESIDENT OF ADMINISTRATION OF A TOOL AND DIE COMPANY IN DAYTON, OHIO. OUR COMPANY IS ONE OF APPROXIMATELY 1,000 TOOL AND DIE COMPANIES IN THE STATE. WE EMPLOY 600 PEOPLE. I AM ALSO PRESIDENT OF THE DAYTON TOOLING AND MACHINING ASSOCIATION; AN ORGANIZATION OF 150 MOSTLY SMALL TOOL, DIE, MOLD AND PRECISION MACHINING COMPANIES IN THE DAYTON AREA.

AS AN EMPLOYER, WE NEVER LACK FOR CHALLENGES. NOT ONLY IS THE WORK THAT TOOL, DIE AND PRECISION MACHINING COMPANIES DO CHALLENGING, BUT WE OPERATE OUR COMPANIES IN A FIERCELY COMPETITIVE WORLD ECONOMY. OVER THE LAST FEW YEARS, WE HAVE WITNESSED A TREMENDOUS INCREASE IN FOREIGN COMPETITION FOR THE PROVISION OF TOOLS, DIES AND PRECISION MACHINING SERVICES FROM OVERSEAS, AND EVEN THIRD WORLD COUNTRIES. THIS HAS PLACED MY COMPANY, AND THE OTHER PREDOMINATELY SMALL TOOL AND DIE SHOPS IN THE U.S., IN A TREMENDOUS COST PRICE SQUEEZE.

MY INDUSTRY IS A HIGHLY SKILLED LABOR AND MACHINE INTENSIVE INDUSTRY. OUR EMPLOYEES HAVE YEARS OF TRAINING PROVIDED BY OUR COMPANIES AND THE ASSOCIATION I REPRESENT HERE TODAY. WE VALUE THOSE PEOPLE VERY HIGHLY. BECAUSE OF THE MUTUAL DEPENDENCY WHICH EXISTS BETWEEN US AND OUR EMPLOYEES, WE HAVE A GREAT CONCERN WITH THEIR HEALTH AND WELFARE, AND WE ALREADY PROVIDE EXTENSIVE MEDICAL AND SURGICAL BENEFITS TO COVER THE OCCURRENCE OF ANY UNFORESEEN MEDICAL DIFFICULTY.

OUR TOTAL BENEFIT COSTS ADD ANYWHERE FROM 30 to 40% TO OUR HOURLY WAGE COSTS. WITH WAGE RATES AS HIGH AS WE PAY, THE COMBINED EFFECT MAKES IT VERY HARD TO COMPETE AGAINST FOREIGN COMPANIES WHO PAY NO HEALTH BENEFITS AND WHOSE WAGE RATES ARE OFTEN A FRACTION OF OURS. IN FACT, IN 1986, THE COST OF PROVIDING HEALTH CARE FOR OUR EMPLOYEES WAS IN EXCESS OF $1.00 AN HOUR WHICH EXCEEDS THE HOURLY LABOR COST IN SOME COUNTRIES SELLING PRODUCTS IN THE UNITED STATES.

S.79 ON ITS FACE WILL ONLY ADD TO OUR COSTS, THEREBY PUTTING US IN A DEEPER COMPETITIVE HOLE. WHAT'S TRUE FOR US IS, OF COURSE, TRUE FOR ALL THE MEMBERS OF OUR ASSOCIATION. I THEREFORE RESPECTFULLY REQUEST THAT THIS SUBCOMMITTEE CONSIDER ALTERNATIVE FUNDING MECHANISMS TO PAY FOR WHAT WE PERCEIVE AS A VERY WELL-INTENTIONED PROGRAM.

THE SUBCOMMITTEE SHOULD ALSO ASSURE THAT CLEAR AND CONVINCING EVIDENCE OF POPULATION AT RISK IS NECESSARY PRIOR TO REQUIRING ANY NOTIFICATION. WITHOUT A LEGALLY DEFINED, ENFORCEABLE STANDARD, THE RISK OF FALSE ALARMS AND BUREAUCRATIC BUSY WORK WILL RUN HIGH.

MR. CHAIRMAN, WHEN YOU MET WITH SEVERAL OF MY OHIO COLLEAGUES EARLIER THIS MONTH AND DURING LAST YEAR'S HEARINGS, YOU INDICATED THE INTENTION THAT THE BILL NOT CREATE ANY UNDUE BURDEN ON EMPLOYERS. IF THE SOLVENTS, CUTTING OILS AND CLEANING AGENTS NECESSARY TO OUR MANUFACTURING PROCESSES ARE FOUND TO BE THE CAUSE OF OCCUPATIONAL DISEASE, THE COSTS OF TESTING AND TREATMENT WILL ULTIMATELY BE REFLECTED IN THE COST OF OUR PRODUCTS. THOSE COSTS COULD BE DIRECT OR REFLECTED IN HIGHER INSURANCE OR CHEMICAL COSTS AS A RESULT OF TESTING, TREATMENT OR LEGAL FEES AND SETTLEMENTS. FOR THAT REASON, IT IS IMPORTANT TO FILL IN SEVERAL IMPORTANT BLANKS IN THE ATTACHED CHART, TO COMPUTE THE IMPACT IN TERMS OF ADDED COSTS TO THE PRODUCT, AND THEN, IF THAT FIGURE IS

SIGNIFICANT, CALCULATE THE IMPACT IN TERMS OF JOBS LOST BY MEANS OF AN ECONOMETRIC MODEL. ONLY WHEN THIS FIGURE IS AVAILABLE WOULD YOU HAVE A MEASURE OF THE DOWNSIDE RISK AND THUS BE IN A POSITION TO DECIDE HOW TO PROCEED.

AMERICAN INDUSTRY IS PRESENTLY BLEEDING TO DEATH. NOT AS THE RESULT OF SOME SINGLE LETHAL WOUND, BUT RATHER DUE TO HUNDREDS OF SMALL WOUNDS EACH SEEMINGLY INSIGNIFICANT ON ITS OWN. ALL OF THOSE WOUNDS WERE INFLICTED WITH GOOD INTENTIONS AND FOR THE GREATER GOOD OF ALL INVOLVED, BUT THE RESULT IS THE SAME. WE HAVE LOST THOUSANDS OF JOBS AND WILL LOSE THOUSANDS MORE UNLESS THE BLEEDING STOPS. BUT THE HEALING PROCESS CANNOT BEGIN UNTIL THE WOUNDING STOPS. THAT IS WHY WE ARE HERE TODAY.

MR. CHAIRMAN, I HAVE ATTACHED TO MY TESTIMONY A TWO-PAGE PAPER OF SUGGESTED TECHNICAL CORRECTIONS TO THE PROPOSED ACT. I HAVE FOCUSED ON THE COST COMPETITIVE ISSUE BECAUSE I THINK IT IS THE MOST FUNDAMENTAL ONE.

I WOULD BE HAPPY TO RESPOND TO YOU AND YOUR COMMITTEE'S QUESTIONS.

HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION

The National Tooling and Machining Association strongly endorses a safe workplace and the identification, notification, and more importantly, prevention of occupational disease. In many respects, the United States had led the world in steps to improve the workplace. Those efforts should continue and should include efforts to require similar standards of workplace safety in other countries.

The latter is essential if the jobs of the workers whose health we are seeking to protect are to be protected as well. The availability of manufacturing jobs in this country is increasingly a function of international competitiveness. Improvements in the workplace environment cost money. Whether that cost be direct or indirect, it will unfairly cost many American workers their jobs if our trading partners do not make similar investments in worker health and safety.

The dilemma is obvious. U.S. manufacturing workers who lose jobs because of increased manufacturing costs will find themselves in a much lower paying service job. They may also suffer unemployment with all the financial and psychological pressures and damages it brings to the worker and the worker's family.

Specific NTMA recommendations to improve the legislation are as follows:

1. Enact, as an amendment to H.R.3, the Trade and International Economic Policy Reform Act of 1987, section 124 (market disruption) the requirements for a tariff equal to the proportionate cost of U.S. worker health/safety programs to manufacturers in any competing nation which a) increases exports of those products into the U.S. over the preceding year, and b) fails to provide commensurate worker safety and health programs for their workers. The determination of the amount of the tariff would be made by the International Trade Commission. Eliminate Most Favored Nation Status on a product line basis for nations meeting criteria a) and b).

2. Modify section 3 paragraph 7 to reflect that "statistically significant evidence" be based on accepted statistical measures of probabilities; that "chronic" health effects must be serious.

3. Expand section 4(b)(B) (information requests) to require the Board's consideration of information volunteered by federal agencies or other organizations pertaining to occupational health hazards.

4. Expand section 5, paragraph b (contents of notification) to include findings of the frequency of incidence in workplace populations versus the public at large.

5. Expand section 5, paragraph g(3) (judicial action) to allow set aside of determination on the grounds of an error or errors in analysis.

6. Clarify section 6(2)(A) to make it clear that a small business may not be required to assume the certification administrative requirements (except for posting, notifying affected present employees, and providing last known address of ex-employees).

7. Modify section 7(a)(1) to allow the establishment and certification of as many health centers as can meet the criteria for selection.

8. Expand section 9 (employee testing) to require all insurance companies to offer insurance to pay for such testing; allow employers impacted by import competition to apply for proceeds of the tariff suggested in recommendation #1 to underwrite all direct or insurance costs of the program (including both testing and treatment), provide an exemption from the benefit reduction provisions for firms with 100 or fewer employees.

FORMULA FOR DETERMINING JOB LOSSES-

EMPLOYER FUNDED OCCUPATIONAL DISEASE NOTIFICATION AND TESTING

Workers Affected	12 Million	(2)
1) Notification Costs (each, optional)	$ 20 - 27.50	(3)
2) Surveillance/Testing Costs (each)	$ 20 - 250	(4)
3) Transportation, Food, Some Lodging (each)	$ 20	(5)
4) Cost of Idle Equipment (each)	$ 133.20	(6)
5) Workers Compensation Rate Increase (current $250 each)	?	(7,8)
6) Health Insurance Rate Increase (current $2,205 each)	?	(9)
7) Additional Legal Fees, Settlements and Judgements	?	(10)
8) TOTAL COSTS	$193.20 - 430.70 plus Line 5 + Line 6 + Line 7	
9) Product Price Increase	Line 8 ÷ Sales Per Employee	
10) U.S. Jobs Lost Due To U.S. Product Price Increase	?	

ENDNOTES

(1) May 15, 1986 Hearing Record, p.193.

(2) 11.925 million workers known to be exposed to carcinogenic or dangerous non-carcinogenic substances (William Winpesinzer, President of the International Association of Machinist) p.217-218, 1986 hearings.

(3) NIOSH estimate (p.56, 1986 hearings), 2/18/87 Wall Street Journal, p.1.

(4) Tests would include, among other substances benzene, asbestos, arsenic, chromium, chromatic pigments, mesa silica or cotton or coal dust. Estimated costs range from $20-200 per test or series of tests. Also "the cost impact of such monitoring could be significant" (statement of John Abbott and Patrick Cormody, May 15, 1986 hearing, p.208). Also 2/18/87 Wall Street Journal article.

(5) "will be made available by such employer at no cost to the employee. . . " p.20 lines 3-4 S.79. There is reason to believe that qualified medical personnel will either not be available or not be geographically convenient to a small manufacturer in a rural area. Reasons for that belief are "there is a lack of adequately trained medical and human service professionals, as well as appropriately staffed and equipped health facilities to recognize, diagnose and prevent occupational illnesses (S.79, findings p.3, lines 12-15) also number of individuals each year to be added to testing program (100,000-300,000) (p.10, lines 15-23). Also the requirement that health centers provide education, training and technical assistance to personal physicians and other professionals serving those employees and offer those services for employees as well (S.79, p.20, lines 13-19) also the requirement that "no school of medicine may receive federal financial assistance. . .unless it offers a course of study on occupational disease (p.22, lines 6-12).

Assumes 1/3 of workers will travel under 10 miles, 1/3 will travel approximately 30 miles, and 1/3 will travel 100 miles (or 47 miles average at $.25 mile) and meals for 20% (@$5.00 each) plus lodging for 10% (@$35.00 each) $11.75 + $1.00 + $3.50 = $16.25

(6) Assumes 1/3 of workers will be out two hours, 1/3 four hours, and 1/3 eight hours. Based on operator of $250,000 machining center, 90% financed at 12% for 5 years or $33.30 per hour.

(7) Unknown "state workers' compensation systems would be inundated with claims because of the fear of becoming disabled". Statement of Charles Coakley, Senior Counsel, American Insurance Association, May 15, 1986 hearings p.199.

(8) Unknown "the cost of health insurance would increase dramatically if S.2050 were enacted". Same.

(9) Unknown "the net result would be an overall increase in claim expenses to the employer". Statement by John Abbott and Patrick Cormody, Health Insurance Association of America p.218.

(10) There are at least some indications this could be high. An Augusta, Georgia company with 800 workers reportedly instigated an employee occupational disease notification program. Aggregate total of damages sought in subsequent employee suits was reportedly $358 million. This works out to $477,500 per worker.

A Febraury 18, 1987 Wall Street Journal article "Lawyers Lead Hunt for New Groups of Asbestos Victims", attorneys are engaging in aggressive client recruitment efforts involving direct mail, and free mobile tests to workers who use the firm to bring suit. The article states that the efforts are swamping court dockets and quotes Calvert Crary of Bear Sterns & Co. who believes the asbestos lawyers are naturally looking to widen their sphere.

While these may be extreme examples, more data is definitely needed on ratios between law suits and settlement costs in occupational disease notification circumstances.

HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION

Specific NTMA recommendations to improve the legislation are as follows:

1. Enact, as an amendment to H.R.3, the Trade and International Economic Policy Reform Act of 1987, section 124 (market disruption) the requirements for a tariff equal to the proportionate cost of U.S. worker health/safety programs to manufacturers in any competing nation which a) increases exports of those products into the U.S. over the preceding year, and b) fails to provide commensurate worker safety and health programs for their workers. The determination of the amount of the tariff would be made by the International Trade Commission. Eliminate Most Favored Nation Status on a product line basis for nations meeting criteria a) and b) and for nations which have achieved competitive industries in those product lines.

2. Modify section 3 paragraph 7 to reflect that "statistically significant evidence" be based on accepted statistical measures of probabilities; that "chronic" health effects must be serious.

3. Expand section 5, paragraph b (contents of notification) to include findings of the frequency of incidence in workplace populations versus the public at large.

4. Expand section 5, paragraph g(3) (judicial action) to allow set aside of determination on the grounds of an error or errors in analysis.

5. Clarify section 6(2)(A) to make it clear that a small business may not be required to assume the certification administrative requirements (except for posting, notifying affected present employees, and providing last known address of ex-employees).

6. Modify section 7(a)(1) to allow the establishment and certification of as many health centers as can meet the criteria for selection.

Senator METZENBAUM. Mr. Tom Evans, speaking for the National Association of Manufacturers, with whom we have had some discussions, and I might say we are open to having additional discussions. As I understand it, there are two points of view in your organization, and the hard line at this moment is the prevailing one, but we hope we can move the hard line to the middle to a sort of cooperative position.

Senator QUAYLE. That is the Quayle proposal, the middle.

Senator METZENBAUM. Well, that is a matter of definition.

Mr. Evans, we are happy to hear from you and are particularly pleased to welcome you here this morning.

Mr. EVANS. Thank you, sir. Please, do not judge me before I speak. [Laughter.]

Senator METZENBAUM. Fair enough, fair comment.

Mr. EVANS. Mr. Chairman, my name is Tom Evans, and I am Director of Safety and Environmental Health at the Monsanto Company, and I really am grateful for the opportunity to be here and testify on behalf of the National Association of Manufacturers.

NAM is a voluntary business association of over 13,000 corporations, large and small, located in every State in the Union. NAM concurs, Mr. Chairman, with the basic goal of the proposed legislation. Although we do not necessarily agree that a significant number of workers suffered death as a result of being exposed to occupational health hazards, one such occurrence would indeed be too many.

We believe very strongly that all employees have the right to know, and indeed must know about the hazards of the chemicals to which they are exposed. We also believe that our employees need to know that they are at risk of contracting an occupational disease, how great that risk is, and to be informed of the signs and symptoms of the onset of disease; and further, that our employees need to know that they will be told that they have been so exposed, and that they need to know that their health will be monitored as well.

Mr. Chairman, we respectfully suggest that to accomplish these goals, a new, costly Federal program is unnecessary. Already, a myriad of regulations require employers to notify current workers of potential hazards. We believe that changes in current regulations could resolve the issue of notifying past employees in a more efficient and simpler manner.

We request that the Congress seriously consider the potential legal liability that such a bill could pose for employers who in good faith are complying with the law.

More specifically, a lot of discussion has been had already about the Hazard Communication Standard, but let me say I do believe it is the most significant piece of occupational safety and health regulation that has been promulgated since the Act itself in 1970. It requires employers to develop a hazard evaluation to identify any substance that may produce an adverse health effect. It requires written training programs, material safety data sheets; it requires labels to give you warnings and other information about chemicals.

In the Superfund Amendment and Reauthorization Act signed into law last November, the Congress wisely, Mr. Chairman, codified the material safety data sheets required by the OSHA standard. This demonstrates, really, that existing mechanisms can be used rather than creating new ones.

If the Congress feels compelled to expand the notification to past as well as present employees, we would recommend using the same approach now used for current employees under the Hazard Communication Standard. Employers, for example, could be required to notify retired employees. The responsibility for notifying orphaned employees could be given to an agency of government.

Concerning the liability crisis, NAM does believe that individual notification as proposed will result in a multitude of tort actions. There must be a provision in this legislation, limiting liability for companies who comply with the notification and prevention requirements. The court dockets are already overwhelmed with such multi-million-dollar tort actions, and without some protection here, neither large nor small business will be able to afford or get general liability insurance.

One of the main concerns with the bill is how high risks will be defined and who will have the responsibility for determining those risks. Principles of good science and human epidemiology must be employed while judgments are based on substantial evidence.

Rather than establishing a Risk Assessment Board, employers could be permitted to continue their same risk assessment procedures with oversight from a more broad-based scientific group comprised of candidates from all disciplines of occupational safety and health.

Additionally, medical monitoring should not necessarily be left to the medical profession. OSHA is in the process of developing a generic performance-oriented medical monitoring standard, and it is NAM's hope that the Congress will defer to OSHA in this area.

In summary, Mr. Chairman, my company and many others are already communicating to their employees about the hazards of risk exposure to chemicals. Any gaps in this regulatory scheme should be filled by additional regulations within the already existing regulatory framework. We urge the Congress to marshal all of these existing statutes, to do the job for which they are capable, rather than adding new burdens. Small business simply will not be able to shoulder the burdens, and big business will probably find themselves spending more time on paperwork than on real health and safety issues.

I really appreciate the time and your listening, and I would be happy to answer any questions. Please do know that we will be happy to work with the Congress on the issues in this legislation. Thank you very much.

Senator METZENBAUM. Thank you very much, Mr. Evans.

[The prepared statement of Mr. Evans follows:]

National Association of Manufacturers

WRITTEN TESTIMONY OF THOMAS EVANS ON BEHALF OF
THE NATIONAL ASSOCIATION OF MANUFACTURERS
ON S. 79, THE HIGH RISK OCCUPATIONAL DISEASE
NOTIFICATION AND PREVENTION ACT OF 1987

BEFORE THE SUBCOMMITTEE ON LABOR

February 24, 1987

1331 Pennsylvania Ave., NW • Suite 1500 - North Lobby • Washington, DC 20004-1703 • (202) 637-3000

Good morning, Mr. Chairman and members of the Subcommittee. My name is Thomas Evans. I am Director of Safety and Environmental Health for the Monsanto Company. I am here today to present my concerns with S. 79, the "High Risk Occupational Disease Notification and Prevention Act of 1987" on behalf of the National Association of Manufacturers (NAM).

The National Association of Manufacturers is a voluntary business association of over 13,500 corporations, large and small, located in every state. Members range in size from the very large to over 9000 smaller manufacturing firms, each with an employee base of less than 500. The NAM member companies employ 85 percent of all workers in manufacturing and produce over 80 percent of the nation's manufactured goods. NAM is affiliated with an additional 158,000 businesses through its Association Council and the National Industrial Council.

INTRODUCTION

The National Association of Manufacturers concurs with the basic goal of the proposed legislation. Although we do not believe that a significant number of workers suffer death as a result of being exposed to occupational health hazards, even one such preventable occurrence would be too many. We believe strongly that all employees have the right to know, and indeed should know, about the hazards of chemicals to which they are exposed and how to protect themselves on their jobs. We also believe that our employees need to know if they are at risk of contracting an occupational disease, how great the actual risk is, and to be informed of the signs and symptoms of the onset of disease.

NAM believes, however, that S. 79 will not achieve these stated goals and will have adverse effects that outweigh any of its beneficial results. We believe a new costly program is unnecessary to achieve the goals outlined.

NAM applauds the various improvements made by Senator Metzenbaum in S. 79 over last session's bill. Progress has been made in eliminating the 30% trigger for defining populations at risk and revising the procedure under which the Risk Assessment Board reaches its determinations about what constitutes a high risk. The bill, however, remains seriously flawed in at least four major ways.

First, many of the bill's mandates are duplicative of the many agency regulations which already exist in the area of worker health and safety. Worker notification of hazards is already comprehensively regulated in the states and at the federal level. An additional and overlapping regulation is unnecessary. Second, the bill will result in an explosion of liability. Individual notificiation as proposed under S. 79, will cause many of the one hundred thousand notified employees to file tort and worker compensation actions against their employers. Absent a solution to this problem, business will face billions of dollars in legal liabilities. The cost will ultimately be borne by employees and consumers. Third, the actual impact of the bill is unknown. The potentially wide-ranging impact of this bill upon employers and employees should be more thoroughly studied before it is passed. Fourth, and finally, the bill itself contains many scientific and legal flaws.

A BETTER APPROACH

We feel strongly that a better approach exists than that proposed by S. 79. Current employees are already being notified under the Hazard Communication Standard, 29 C.F.R. Sec. 1910.1200 (1986). This comprehensive Standard should not be duplicated. If Congress is intent on notifying all past employees of hazards, we would urge you to do it within the context of existing regulations. It is possible that industry could notify retirees and the government could undertake the responsibility of notifying other past employees. Moreover, many chemical companies already have risk assessment procedures and should be permitted to continue with their own programs, with some oversight from a broad-based scientific advisory group.

In the Superfund Amendment and Reauthorization Act signed into law in November of last year, the Congress codified the material safety data sheets required by the OSHA Standard. This example demonstrates that existing mechanisms can be used rather than creating new ones. NAM's current policy supports the concept of working within the existing regulatory framework rather than creating an entirely new regulatory scheme.

NAM understands that Senator Quayle is working on an alternative approach to S. 79 and we plan to give it careful review and consideration. The very existence of this alternative reflects a lack of concensus on the best approach to the occupational disease notification issue. We would like to thank the Senator for considering a new approach and thereby attempting to avoid some of the problems inherent in S. 79. We have below further elaborated on the problems of S. 79.

THE BILL IS REDUNDANT AND IS UNNECESSARY

Most of the goals of S. 79 are being achieved or are achievable through existing statutes and regulations. We already have agencies and legislation such as the Occupational Safety and Health Administration, the Environmental Protection Agency, the National Institute for Occupational Safety and Health, the Consumer Product Safety Commission, the Food and Drug Administration, the Center for Disease Control, the Toxic

Substances Control Act, the Federal Insecticide, Fungicide and Rodenticide Act, the Superfund Amendments and Reauthorization Act, and the Resource Conservation Recovery Act. All of the above agencies and laws deal in some degree with the prevention of adverse health effects from toxic substances and harmful physical agents.

Directly on point, the Occupational Safety and Health Administration promulgated the Hazard Communication Standard, 29 C.F.R. Sec. 1910.1200 (1986). This Standard requires manufacturers to evaluate every substance they produce to determine whether there are possible adverse health effects from exposure to the substance. This is the most comprehensive regulation promulgated since the passage of the Occupational Safety and Health Act itself. Under the Standard, companies must develop a comprehensive material safety data sheet (MSDS) which must report the existence of even one study which demonstrates a harmful effect. In addition, containers must be labeled with the identity and hazard presented by the substance. Every employee in a United States manufacturing plant who has any likelihood of being exposed to a hazardous substance must receive training through the employer's hazard communication program and must have access to relevant material safety data sheets. The employer must provide additional training each time a new hazard is introduced into the workplace and update the material safety data sheet each time new relevant information is learned about the substance.

We urge a more thorough assessment of the effectiveness of this program rather than rapidly pushing legislation that will in most ways overlap. The Hazard Communication Standard just went into effect on May 25, 1986 and the Occupational Safety and Health Administration is enforcing it. The agency has already issued over 10,000 citations. Moreover, the agency has announced that it will soon expand the Standard to cover all employers.

In addition to the Hazard Communication Standard, information on workers' exposure to chemicals is available to them under OSHA's Access to Employee Exposure and Medical Records Rule which has been in effect since August 1980. The Access Rule contains a specific provision that employers must inform employees of the existence, location, and availability of medical records and must also inform them of their rights of access to those records. The Access Rule also grants former employees the right of access to these medical records.

OSHA also has twenty-two health standards that mandate medical surveillance at no cost to employees and OSHA must address the issue of medical monitoring in every new health standard it promulgates. Moreover, sections 20, 21, and 22 of the OSHA Act already grant to the National Institute for Occupational Safety and Health the authority and the responsibility to engage in establishing occupational and environmental health centers to conduct research on job-related disease, a specific provision of S. 79. The Institute has already established guidelines for notification of employees clearly identified as "at risk" in its studies. In addition to the federal regulations, at least forty-three states and jurisdictions have implemented worker "right-to-know" legislation or regulations.

Given the multitude of comprehensive federal and state regulations which already exist in the worker health and safety area, NAM urges the Congress not to create a new agency. Such duplicative regulation can only make America's industry move further into the noncompetitive realm.

THE BILL WILL RESULT IN AN EXPLOSION OF LIABILITY

Perhaps the greatest problem posed by your legislation is the potential for unwarranted lawsuits for employers who in good faith comply with the law. S. 79 will serve as a catalyst for litigation against employers. Under the bill, a minimum of 100,000 people, and a goal of 300,000 people, will be notified each year even though very few, if any, will actually develop an occupationally-related disease. Those notified will undoubtedly seek damages, even if just based upon their fear of contracting a disease. Legal precedent exists which holds that the fear of contracting an illness is a compensable injury.

In 1980, for example, approximately 800 employees of one company in Augusta, Georgia, were notified that they were at an increased risk of disease. As a result, $335 million in lawsuits were filed against an already bankrupt company. S. 79 calls for a minimum of 100,000 employees to be notified per year. If only ten percent of those notified sue and recover an average of only $100,000 in damages (or an employer incurs only $100,000 in legal fees in defending the suit), it will cost American business, and ultimately the American consumer, one billion dollars every year. If the goal of notifying 300,000 employees is achieved, the cost will rise to three billion dollars.

S. 79 offers inadequate protection from this very real threat of liability. If the drafters of this legislation are sincere in their intent to use this bill only as a means to inform employees of occupationally related health risks and to provide medical monitoring, this avenue of litigation should be walled off. NAM promises to work with the Subcommittee to accomplish this goal.

THE ACTUAL IMPACT OF THIS BILL IS UNKNOWN

The actual impact and ramifications of S. 79 are unknown and should be more thoroughly researched before a bill of this magnitude is enacted. The cost of medical monitoring, for example, is virtually unknown and probably outside the reach of the nation's thousands of small businesses. Although NAM does not oppose the concept of legitimate medical monitoring when it will serve a beneficial purpose, NAM is concerned that such monitoring will be subject to various types of abuse, similar to the abuse experienced by the Medicare and Medicaid programs. Such abuse will cause the price tag of this monitoring to skyrocket past the means of most companies, especially small companies.

The overall impact of this bill on small businesses is another area which has not been studied. Many of these businesses will be unable to handle the costs of this bill. Medical monitoring, additional paperwork, and increased insurance premiums will all take their toll. The impact on small business must be more carefully examined prior to the passage of this potentially devastating legislation.

THE BILL CONTAINS SERIOUS SCIENTIFIC AND LEGAL FLAWS

S. 79 contains serious scientific and legal flaws. The bill, for example, does not provide the necessary expertise for sound decision-making. A politically appointed five-member Risk Assessment Board would be created that is composed exclusively of Public Health Service employees. The Board will have essentially unreviewable discretion to make broad determinations with devastating impact based upon vague guidelines and faulty science. We think a better approach would be to allow industry to continue to make its own risk assessments in accordance with the dozens of other regulatory guidelines. An overview process might prove necessary, but the establishment of one should certainly include a board composed of the most qualified experts without the artificial constraints as to whether they are employed by the private or public sector or academia.

S. 79 uses a scientifically unsound approach to identify workers at risk. Notification could be triggered by just one "statistically significant" animal or laboratory study indicating that acute or chronic health effects may occur in exposed employees. This loose test will require notification of workers who are not, in fact, at risk. Sound scientific principles require the consideration of medical and epidemiological evidence, biological plausibility, and other relevant criteria in addition to statistical significance. Moreover, one study is an inadequate basis of determination.

S. 79 is erroneously based upon the concept of increased risk as opposed to high risk notification. A statistically significant increase in a small risk could still present just a small risk, not a high risk. S. 79, however, would require that this extremely small risk be addressed. The result would be a potentially large population of highly anxious workers concerned about an extremely small risk. The medical implications of this anxiety could far exceed the medical implications of the risk itself.

S. 79 contains a completely arbitrary and unscientific quota for notification. Not less than 100,000 employees must be notified per year, with a goal of 300,000 employees per year. Under this provision, 100,000 employees would have to be notified each year even if there were no medical necessity. This requirement should be eliminated.

S. 79 fails to provide a proper test for judicial review. The bill requires that the determination of the Secretary of the Department of Health and Human Services may be set aside if it is "arbitrary, capricious or an abuse of discretion." Where, as here, critical issues of fact are involved, the crucial findings should be supported by the evidence on the record. The appropriate test is the "substantial evidence test."

NAM furthermore does not believe there is justification for the creation of additional state education and research centers; if more research is needed, NIOSH should be funded accordingly.

CONCLUSION

Many of our companies are already communicating to their employees about the hazards and risks of exposure to chemicals. The existing law that requires manufacturers to do this is sufficient for current employees. Notification of past employees could be done within the existing framework already in place. Rather than taking the approach set forth in S. 79, we urge that the bill be used to marshall the current statutes to do the job for which they are capable.

Senator METZENBAUM. We have about 12 minutes before we are going to have to close down this hearing, and I will try to be brief.

Mr. Cheek, you mentioned the cost savings that will result from reducing the incidence and severity of disease. Is this bill going to save employers money in the long run?

Mr. CHEEK. It is my judgment that it can, Senator. If careful attention is paid to limiting the front-end liability costs, I think over time this bill certainly will save employers money through the reduction in disease incidence and also through the reduction in the cost of treating those diseases when they occur.

Senator METZENBAUM. As you know, Mr. Cheek, we have already made a number of compromises and concessions in order to try to bring onboard some of those who are not presently onboard. Are you prepared to work with us and to meet us halfway? We are not going to go all the way to where you or Mr. Finnigan or Mr. Clark would hope that we would go, but I think that if we are prepared to meet you halfway and make some concessions that we might not otherwise be inclined to make, is the group that you represent then prepared to support the legislation?

Mr. CHEEK. I would say, Senator, that it is our hope that the improvements that we have been talking about this morning will be extensive enough to at least enable us to withdraw our opposition to the bill——

Senator METZENBAUM. That is not my question.

Mr. CHEEK. I know.

Senator METZENBAUM. I am not interested in your withdrawing your opposition. We have got plenty of opposition without you.

Mr. CHEEK. I understand that, I understand that. You did not let me complete——

Senator METZENBAUM. I am interested in whether we can get you onboard.

Mr. CHEEK. The next phrase in my sentence was—"if not to actively support it."

Senator METZENBAUM. All right.

Mr. CHEEK. We believe it is a little too early to be able to know whether the changes that we and others believe are necessary will be acceptable to the other interested parties in this process—organized labor, yourself, your staff—and therefore we cannot really forecast now exactly where we will come out. Let us just say that the spirit is willing, and we hope it will turn out that way.

Senator METZENBAUM. All right. Well, we want you as an enthusiastic supporter.

Mr. CHEEK. We will do the best we can, Senator.

Senator METZENBAUM. How about you, Mr. Finnigan?

Mr. FINNIGAN. Well, sir, we would really like to see, as we have already stated here, a lot more scientific process, good science, put into this bill. I think our paper as presented and as written really stresses this.

I think that certainly we would feel a lot better about the bill if it has been beefed up in a scientific way, as we have talked about. I think we would like to see the bill in its entirety before we are willing to state our final position on the bill.

Senator METZENBAUM. But you do not have any reservations provided we can make those accommodations you are concerned about to then be in support of the legislation if and when that can occur?

Mr. FINNIGAN. Well, I think we would like to reserve the opportunity to see the bill in its final form before making that statement, sir.

Senator METZENBAUM. Well, I want to say to all those who are interested, the Chair is not new to the legislative process, either here or back when he was a member of the legislature in Ohio and also even when I was a lobbyist. But I have always thought that the sine qua non in this kind of process is that once you make your compromises, once you do that, you just do not get somebody to quit being your opponent because, as I have already said, we have got a heck of a lot of opponents out there that we are never going to be able to satisfy and who are just determined to sink the bill.

We are looking for some of you to come onboard as strong supporters. That to us is the objective in working with you—not to just make the compromises and weaken the bill, only to have you say, "Well, we are still opposed to it." So let that at least be my message to you.

Mr. FINNIGAN. Well, we would really like to work with you, Senator, in carrying out the changes and helping it to become what we think is a good bill.

Senator METZENBAUM. Thank you very much.

Mr. Clark, would you care to address yourself to that?

Mr. CLARK. Yes, Mr. Chairman.

We have briefly reviewed Senator Quayle's outline draft, and our initial reaction strictly from a competitive standpoint is that it would have a lesser economic impact. We believe that both it and S. 79 should be considered from the standpoint of impact on jobs.

I think our major concerns are probably in three areas: number one, the impact on jobs, and the concern that we would be transferring public health care costs to the private employers; and thirdly, that we do not spawn a whole new level of costly litigation that would again cost the employers far in excess of what they can afford today. I am particularly sensitive to that with what I have been through in the Ohio workmen's comp situation recently, and I think you are probably aware of that.

Senator METZENBAUM. The bell has rung on me, but I think I will ask Mr. Evans a question. Is there any possible way that we can bring the NAM onboard to support this legislation, or is that beyond the realm of hope?

Mr. EVANS. I do not think anything is beyond the realm of hope in this world, Senator. NAM is not opposed to the concepts. Please understand that. But there is a vision here that there are mechanisms today that exist that can be expanded, truly expanded, within the same frameworks to require almost every feature of the bill that exists. Medical monitoring could be imposed by OSHA, a generic medical monitoring standard, which would cover that aspect of the legislation. A risk assessment should be allowed—the employers of the world should be allowed—I am in the chemical industry, and it is easy for me to talk about the ease of the ability that we have to do risk assessments and evaluate the hazards of the chemicals. It is the small businesses that I think have the trouble here; they can rely on the information we provide, through the mechanisms of an expanded Hazard Communication Standard—that we understand is going to happen; the Administration has announced that they intend to do that—and if these same mechanisms could be used to incorporate these other requirements and needs, including some kind of science advisory group with representatives from all phases of occupational safety and health, they could be the backup oversight to this.

Seriously, Senator, in all due respect, I do not understand how the government can undertake this job on their own. If the government is going to do the risk assessment, and they are going to do the notifying, I truly do not believe there are enough toxicology labs and resources of people in the country to do this.

We should be required to do this. Good companies that make their chemicals do this today. They evaluate them, they assess the risks, and they should communicate to their employees. They could be mandated to communicate to retired employees through an extension of the standard if necessary.

We are not opposed to informing our people, and goodness knows, it is to everybody's benefit to prevent as much as possible the onset of any disease. We just strongly urge that there be a scientific process involved, and give us that job; do not let the government do it. I do not think the taxpayers can afford it, and we are more qualified, and with a group to oversee us to be sure that we do our job properly, we would be more interested in working with the Congress in this area.

Senator **Metzenbaum**. Thank you, Mr. Evans.

Senator Quayle?

Senator **Quayle**. Thank you, Mr. Chairman.

Let me see if I can get an agreement on some of the fundamental concerns that you all have with S. 79. I think for the purpose of trying to get an appreciation of that, I found the most succinct expression of concern comes from Mr. Cheek's testimony on page 2. I am going to ask Mr. Finnigan, Mr. Evans and Mr. Clark if they agree that these are the two most fundamental problems in S. 79.

First, is that employees should be notified that they are at risk of disease only when it is certain that they have been exposed to an occupational health hazard; and second, is that a disease notification and prevention program should neither serve as the basis for establishing the liability of an employer or a product manufacturer for permitting or creating an occupational health hazard, nor have any bearing on claims under existing law for harm arising out of an occupational health hazard.

Now, those are the two concerns and central principles advocated by Mr. Cheek, and I think it has been picked up by the other witnesses as I have listened. Could we get some sort of feeling—is he pretty much on-target with what your concerns are with S. 79?

Mr. Finnigan?

Mr. **Finnigan**. Well, Senator Quayle, it is our feeling that we really need a strong scientific content. I have suggested the involvement of a scientific advisory board.

Senator **Quayle**. Would that not be included when he says "first, that the employees should be notified that they are at risk of a disease only when it is certain that they have been exposed to an occupational health hazard"? Doesn't that address some of the scientific concerns you have?

What I am trying to focus on are a couple of fundamental points. As Senator Metzenbaum tries to work with people to see where we may be able to go, it would be helpful, I think, from his point of view to understand what our two central concerns are. That is what I am trying to establish today with the very fine witnesses here.

Mr. FINNIGAN. My concern is whether or not we have a scientific basis that involves, for instance, peer review as opposed to the basis proposed in the bill where the Risk Assessment Board is more or less the determining authority. I really believe we need a scientific review panel that would go through their findings and bring a peer review aspect into it before we pick out a group of people who are either involved in a study or, as proposed in your bill, a group that we are extrapolating to that were not involved in the study.

Senator QUAYLE. You have looked at our approach, and it would satisfy that concern, wouldn't it?

Mr. FINNIGAN. Yes, I think so. In fact, we think from AEA that many of the objectives and functions that you have brought out in your bill really could be incorporated into the Metzenbaum bill, really through the amendments that we have proposed regarding a scientific advisory board.

Senator QUAYLE. Mr. Evans, are those two central principles pretty much on target, what we are talking about as concerns with the bill?

Mr. EVANS. I am not qualified to talk about the liability, certainly, but from what I know about the members of NAM and any small business around the country, or even large businesses, the concern is real, because we are all experiencing tort actions today, and they just continue to proliferate in the courts. So we certainly are concerned about that.

In terms of the notification, I am not a doctor, but I guess I have gotten to know a lot of them over the last few years a well as epidemiologists in this business. We talk about evaluating our chemicals, Senator, under a hazard evaluation program which is based on any significant scientific evidence in the literature that is shown to prove a health effect. Now, this is primarily animal data that we are dealing with. In order to transfer that, then, to the employees, and the Hazard Communication Standard requires it, we are required to inform them and show them what these hazards are and what these significant studies are. Now you move into risk assessment. Here, we call upon good science, epidemiology and the like. We need human evidence.

So, to notify retired employees and current employees that based on just one animal test that they may be at risk is excessive. We give them the warning, they know the hazards, and they know what to look for.

Senator QUAYLE. You are not opposed to giving notification in certain cases.

Mr. EVANS. Absolutely not, and we do it today.

Senator QUAYLE. Okay. So that would go to this first principle, I think.

Mr. EVANS. We do it today.

Senator QUAYLE. Mr. Clark, very briefly.

Mr. CLARK. Certainly. I certainly agree with those two concerns as being major points. Again, I must reiterate our third concern of unseen costs falling on the backs of the employers that would in fact result in the loss of jobs to foreign competition.

Senator QUAYLE. Mr. Cheek, on these two principles, which I think strike right at the heart of the concerns that I have, have you had a chance to look at our approach, and if so, do they address these concerns that you raise in your testimony?

Mr. CHEEK. They do, Senator. We are very attracted to your bill. We think its primary focus is assuring that good science is used in the notification process, and this is a matter of serious concern to the entire business community given the "junk science" that is paraded forth in toxic tort and workers' compensation cases without any kind of judicial control.

We think that the data reliability and the significance of the health risk, and the intensity and duration of exposure concepts that your bill incorporates would go a long way toward making sure that good science does underlie the risk notification process.

Senator QUAYLE. Finally, one question. Looking at the whole Federal liability standard, if we get into that, aren't we really paving the way for new Federal occupational disease law? Isn't that clearly the direction we are going?

Mr. CHEEK. That seems to be the way it is going. Beyond the cost problems that involves, I am not so sure where that liability would lie. In both workers' compensation and group health insurance programs, normally, benefits are paid only when there is an illness or an injury that results in disability.

Here, we are talking about a standard that relates to the provision of medical surveillance where the claimant may not have any clinically-diagnosable illness or disease. It is hard for us as insurers to picture where that liability will lie. But I will tell you that, as an industry that prefers to be regulated at the State level, we are troubled as a matter of precedent by the imposition of a requirement that there be medical monitoring.

Senator QUAYLE. Thank you very much.

[Additional material supplied for the record follows:]

American Association of Nurserymen, Inc.
1250 I Street, N.W., Suite 500, Washington, D.C. 20005 (202) 789-2900

STATEMENT
before the
SUBCOMMITTEE ON LABOR
of the
COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
FEBRUARY 24, 1987

Thank you Mr. Chairman.

The American Association of Nurserymen welcomes this opportunity to comment on S.79 - the High Risk Occupational Disease Notification and Prevention Act of 1987.

The American Association of Nurserymen ("AAN") is the national trade association of the nursery, landscape and garden center industry. AAN represents more than 3,500 firms engaged in all aspects of the green plant industry -- including the grower, wholesale and retail segments. It is estimated that in the United States in 1985 the retail value of nursery products sold was $5.4 billion. The nursery growing segment of the industry alone employed a basic year-round workforce in 1985 of approximately 43,000 which rose to nearly 102,000 workers during the seasonal peak periods. By almost any standard, our members and the industry itself are composed predominantly of small family-owned businesses, namely nursery farms, landscape firms and retail garden centers.

A Family of Associations: Garden Centers of America, Horticultural Research Institute and its Endowment Fund, National Association of Plant Patent Owners, National Landscape Association and Wholesale Nursery Growers of America.

The American Association of Nurserymen and our members steadfastly share the desire to protect workers from any occupationally -- related health hazards. We believe that all reasonable precautions should be taken to minimize any such potential hazards. The nursery industry's commitment to protecting workers is unshakeable, but we seriously question whether S.79 is needed, workable or even approaches its ostensible goal to protect workers from occupationally-related diseases.

S.79 would establish a new federal program to identify, notify and monitor groups of employees exposed to occupational health hazards. S.79 provides that the findings of merely a single scientific study would be sufficient grounds to set into motion the notification of an entire employee population (present and former workers) that they are at a seemingly high risk of contracting a disease. Given the preponderance of scientific studies and results which can be found to be contradictory, it seems clear that this legislation holds the potential to prey upon the emotions and fears of workers. While S79 contains an elaborate program for notifying employee populations that they have been found to be at risk of disease, the bill is woefully deficient as it does not establish a de-notification program should later or different findings demonstrate that such a risk in fact does not or no longer exists.

S.79 encourages notified employees to seek testing, evaluation and medical monitoring. S.79 provides that such costs shall be borne by the current employer if the exposure occurred during his/her current employment. We truly wonder whether the proponents of S.79 have seriously considered the impact of these financial costs upon the nation's employers and the rippling effects it will have throughout the national economy as a whole. This concern becomes magnified as section 4(b)(3)(C) mandates that, at the very minimum, 100,000 workers per year must be notified and that every reasonable effort shall be made to notify at least 300,000 employees every year. However, this does not take into account any possible scenarios where occupationally -- related health hazards are identified but are determined to affect a much smaller universe of exposed employees.

In addition, S.79 provides that if there is a medical determination that an employee should be transferred to a less hazardous or nonexposed job, the employer must comply and maintain the same level of earnings, seniority and benefits -- whether or not such a position is available. We recognize the desire to protect workers from occupationally -- related health hazards, but who is going to protect the employer if he/she is forced to dramatically alter or even shut down business operations when an occupationally -- related health hazard is suddenly discovered through no fault of the employer?

We also wonder whether the proponents of S.79 have seriously investigated the demonstrable impact that the notification program will have upon medical insurance programs, workers' compensation systems, product liability, and tort claims against employers. AAN believes that S.79's enactment will cause liability, health insurance and other legal costs to employers to skyrocket at a time when the nation, and particularly the business community, is already trying to weather the current liability crisis. S.79 stands to prompt unnecessary litigation when employee notifications are issued on the basis of faulty or inadequate evidence.

S.79 would authorize $25 million for each of the next two years for the government to carry out these programs. However, we strongly suspect that this figure is woefully unrealistic. It is beyond comprehension that such monies could pay for the costs of locating, notifying and counseling affected individual workers -- not to mention the eventual establishment and certification of at least one health center in each State. Besides, no matter how one squeezes a turnip, one still cannot get $5 billion out of $50 million under Section 14 -- even if it is for laudable research purposes.

Perhaps the biggest and most troubling concern posed by S.79 is that the bill would establish a massive new federal bureaucracy which will directly and unnecessarily overlap with existing and expected programs. First, in May 1986, the Occupational Safety and Hazard Administration ("OSHA") broadened and strengthened the Hazard Communication Standard program. This program requires employers who manufacture, distribute and import hazardous substances to notify employees of potential workplace hazards and train those employees in safe handling of such substances. It is widely known that OSHA is considering how to expand the coverage of the Hazard Communication Standard program to all industries where jobs involve exposure to hazardous substances. Secondly, the Environmental Protection Agency is expected soon to issue regulations proposing so-called Farmworker Protection Standards. Such regulations are expected to address the notification and training of nursery industry employees with respect to potentially hazardous chemicals. Third, States and localities are adopting community right-to-know laws whose objectives are again the identification and notification of potentially hazardous substances. In light of the above, S.79 is not only unnecessary, but it would likely lead to conflicting regulations compounding an already well-regulated area.

Despite its stated objective to "prevent illness and death" of employees due to occupationally -- related health hazards, there is nothing in S.79 which poses a preventive measure. The legislation merely requires employees to be notified after high risks to health hazards are determined. The bill does nothing to lessen that exposure in the first place.

In conclusion, the American Association of Nurserymen maintains that the primary objectives sought by S.79 are already in place and working. It appears that proponents of S.79 have not carefully weighed the exceeding costs such an additional program would have upon employers and their insurance providers. We believe it is inevitable that S.79 would eventually work at crossroads, rather than in tandem, with the existing and expected regulatory framework. The American Association of Nurserymen vigorously opposes S.79 and urges the Members of this Committee to do the same.

Thank you.

NATIONAL ASSOCIATION OF WHOLESALER-DISTRIBUTORS

STATEMENT OF

NATIONAL ASSOCIATION OF WHOLESALER-DISTRIBUTORS

BEFORE THE

SUBCOMMITTEE ON LABOR OF THE
COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

ON

S. 79, HIGH RISK OCCUPATIONAL
DISEASE NOTIFICATION AND PREVENTION
ACT OF 1987
FEBRUARY 24, 1987

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SUMMARY

The central purpose of the High Risk Occupational Disease Notification and Prevention Act of 1987 -- to enhance the health and safety of American workers by alerting them to the potentially harmful effects of workplace exposures to hazardous substances -- is a goal that the National Association of Wholesaler-Distributors (NAW) shares with the sponsors of the Act. Workers have a right to as healthy and safe an occupational environment as is feasibly possible, and NAW members recognize the central and indispensible nature of their responsibility as employers in that regard.

Despite the laudable purpose of this proposal, NAW is deeply troubled by the regime contemplated by the architects of the Act as well as the likely effects, whether or not intended, of its enactment into law.

NAW opposes the High Risk Occupational Disease Notification and Prevention Act of 1987 for four basic reasons:

- First, it is largely duplicative of existing law and thus unnecessary;
- second, the Act would lead to an explosion in workers' compensation claims, tort claims brought by employees against their employers, and third party product liability suits;
- third, the Act would exacerbate the acute insurance crisis confronting business generally and small business in particular;
- fourth, the anti-discrimination provisions of the Act create hurdles that most wholesaler-distributors would find enormously costly to clear.

STATEMENT OF THE NATIONAL ASSOCIATION OF WHOLESALER-DISTRIBUTORS

Mr. Chairman and the members of the subcommittee, the National Association of Wholesaler-Distributors (NAW) appreciates this opportunity to present our views concerning S. 79, the High Risk Occupational Disease Notification and Prevention Act of 1987 (the Act).

The National Association of Wholesaler-Distributors: The National Voice of Wholesale Distribution.

NAW is a federation of 124 national (see Appendix A) and 50 state and regional wholesaler-distributor trade associations, with an aggregate membership of 45,000 firms operating at approximately 150,000 locations throughout the nation. Wholesaler-distributors provide the critical link in the marketing chain between manufacturers and all product users. While NAW members range from very small to very large firms, the industry is dominated by small to mid-size, closely-held, labor intensive businesses providing stable, well-paying jobs to over 5 million Americans.

NAW members distribute and wholesale every conceivable consumer and industrial product, and account for approximately 60 percent of the industry's total sales volume -- approximately $1.4 trillion in 1985.

I. INTRODUCTION

Mr. Chairman, the objective of this legislation -- to enhance the health and safety of American workers by alerting them to the potentially harmful effects of workplace exposures to hazardous substances -- is one that wholesaler-distributors and all employers share with their employees. Wholesaler-distributors believe that workers have a right to as healthy and safe an occupational environment as is feasibly possible, and recognize the central and indispensible nature of their responsibility in that regard.

The laudable purpose of the proposal notwithstanding, NAW is deeply troubled by the regime contemplated by the architects of the Act as well as the likely effects, whether or not intended, of its enactment into law.

NAW opposes the High Risk Occupational Disease Notification and Prevention Act of 1987 for four basic reasons:

- First, it is largely duplicative of existing law and thus unnecessary;

- second, the Act would lead to an explosion in workers' compensation claims, tort claims brought by employees against their employers, and third party product liability suits;

- third, the Act would exacerbate the acute insurance crisis confronting business generally and small business in particular;

- fourth, the anti-discrimination provisions of the Act create hurdles that most wholesaler-distributors would find enormously costly to clear.

II. THE HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987 IS UNNECESSARY.

Mr. Chairman, witnesses who have appeared before this subcommittee and other congressional panels have identified and discussed the plethora of federal agencies that are currently engaged in the extensive effort to prevent the contracting of diseases that may result from exposures to hazardous substances. Of particular relevence to the kinds of exposures contemplated by the legislation now before this subcommittee is the

Occupational Safety and Health Administration's Hazard Communication Standard (OSHA HCS)[1], the central purpose of which is to reduce the incidence of chemically-related occupational illnesses. In promulgating its Final Rule on November 25, 1983[2], OSHA expressed the view -- a point of view we fully share -- that "increased availability of hazard information will assist employers in these industries to devise appropriate protective measures, and will give employees the information they need to take steps to protect themselves."[3]

The HCS has been characterized as OSHA's most extensive regulation both in terms of its scope and its expense. It affects more employers than any other OSHA regulation and imposes a substantial compliance burden on chemical manufacturers and distributors, and employers. According to OSHA's Office of Regulatory Analysis, the initial cost of the HCS is nearly $604 million, with subsequent annual costs in the $160 million range -- all of which will be borne by the private sector.[4]

While members of this subcommittee are familiar with the details of the OSHA HCS, a brief review of the Standard's basic scope and content is appropriate. The HCS is a "two-tiered" performance standard. "Tier-1" requires chemical suppliers to ship labelled containers and to provide certain downstream users with Material Safety Data Sheets (MSDS). In general, a manufacturer, importer or wholesaler-distributor who supplies hazardous substances to a covered employer must take the following steps:

1) Evaluate and determine if the substance is hazardous.

2) If it is determined to be hazardous, a Material Safety Data Sheet (MSDS) must be prepared (or obtained from the supplier of the substance as the case may be).

3) A label which shall have a form of hazard warning must be prepared (or obtained) and that label must be affixed to containers in which the substance is to be shipped to downstream users.

This "tier" of regulation went into effect on November 25, 1985, just fifteen months ago.

"Tier-2" of the OSHA HCS applies to the users of hazardous substances. It requires employers to provide information to their employees concerning hazardous chemicals by means of hazard communication programs including labels, material safety data sheets, training and access to written records."[5] To satisfy the requirements of the HCS, covered employers must:

1) prepare a hazard communication program which is a formalized plan stating what the employer is doing to comply with the HCS;

2) determine what hazardous substances are in the workplace and prepare a list of such substances which shall be made accessible to all employees;

3) post required signs to inform those employees engaged in the manufacturing (i.e., blending - machine shop - etc.) operation of (a) the substances to which they are exposed and (b) their right to obtain information concerning such substances;

4) obtain, maintain, file and make available to employees, or their designated representatives, a material safety data sheet (MSDS) for each hazardous substance in the workplace;

5) implement a program to inform employees on how to read an MSDS;

6) maintain labels on containers of hazardous substances in the workplace. This includes the obligation to relabel where mixing takes place and the original label supplied by the first tier supplier is no longer accurate; and

7) develop and implement a training program for employees to (a) make them aware of the hazards; (b) to provide instructions for safe handling under normal operating conditions; and (c) to know the procedures to be followed in emergency situations.

These "Tier-2" requirements went into effect on May 26, 1985, a mere nine months ago.

We would point out at this juncture that despite the supposedly "limited" application of "Tier-2" rules to employers in the manufacturing sector, many wholesaler-distributors are in fact subject to the HCS' embrace. A recently-issued OSHA compliance directive provides that a manufacturing operation that takes place within a non-manufacturing operation constitutes "miscellaneous" manufacturing under Standard Industrial Classification Code 39 and is thus covered by the HCS.

We would also note that OSHA, in response to the May 1985 decision of the U.S. Court of Appeals for the Third Circuit in United Steelworkers of America v. Auchter[6], is now in the process of preparing a proposed rule expanding OSHA HCS coverage to non-manufacturing sectors of the economy. On November 27, 1985, just two days following the effective date for "Tier-1" of the OSHA HCS and nearly six months prior to full HCS implementation, OSHA issued an Advance Notice of Proposed Rulemaking in that regard[7], to which NAW responded with formal comments on February 24, 1986 (see Appendix B).

Finally, we would remind the subcommittee that the Occupational Safety and Health Administration and other federal agencies are not alone in addressing these concerns. Indeed, more than 30 states have adopted "Right to Know" laws, a number of which go beyond the OSHA HCS and cover community right-to-know and/or workplaces other than manufacturing[8], including wholesale distribution.

Thus, wholesaler-distributors are today confronted with the rather delicate, confusing, and expensive task of developing compliance programs directed at applicable state law and the OSHA HCS in an evolving and highly uncertain atmosphere.

Mr. Chairman, the important task of notifying employees at risk of contracting disease as a result of workplace exposures to hazardous substances is already being vigorously pursued. We fully concur in the views expressed by then-Acting Assistant Secretary of Labor for Occupational Safety and Health Patrick Tyson, in testimony presented before the Senate Labor Subcommittee on May 16, 1986, that the OSHA HCS "provides a more efficient, broader, and more effective vehicle for communication" and that pre-exposure notification and employee training as mandated by the HCS "is likely to have a greater impact than a notice"[9]. We believe that the OSHA HCS will thus contribute a great deal more to the prevention of occupational disease than the High Risk Occupational Disease Notification and Prevention Act of 1987 can ever hope to achieve.

Enactment into law of the legislation pending before this subcommittee, while well-intentioned, will unnecessarily add both complexity and cost to an already complex and expensive task. We respectfully submit to the subcommittee that a more appropriate course at this juncture is to give the OSHA HCS a fair opportunity to work.

III. THE HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987 WILL LEAD TO AN EXPLOSION OF WORKERS' COMPENSATION AND TORT CLAIMS.

Wholesaler-distributors are both employers and product suppliers. As the employers of some 3 million of the 5 million individuals employed in the wholesale distribution industry today, NAW members are deeply concerned about the effect that the notification contemplated by the Act will have on the volume of workers' compensation claims and tort claims filed by employees against their employers alleging an "intentional tort." Simply stated, no practical way exists for an employer or his workers' compensation insurance carrier to accurately predict this legislation's impact in that regard. Nonetheless, we cannot conceive that broad notification of individuals that they are at "high risk" of contracting a serious illness due to the presence in the workplace of a dangerous substance would generate anything less than an explosion of such claims.

The fact that many of these claims would be generated by the fear of illness ensures that employers and their insurers will be faced with the inestimable costs associated with "stress claims" filed by individuals who do not and will never suffer from the disease specified in the notification. Additionally, notification such as that proposed in the Act would require employers and their insurers to shoulder the equally inestimable costs associated with claims filed by individuals in the notified population who do in fact suffer from the specified disease but who cannot demonstrate that the illness is the result of a workplace exposure.

As suppliers of products used in the workplace, wholesaler-distributors are concerned that the inability of claimants to recover any, or what they would consider adequate, workers' compensation benefits following notification will give rise to an explosion in third party product liability suits. We are particularly troubled about the likely impact of the Act in that regard given the atmosphere of nearly total unpredictibility and chaos in our product liability tort litigation system today, coupled with the propensity of courts to expand theories of liability by leaps and bounds.

Excellent examples of such developments were provided by Victor E. Schwartz, Esquire, of Crowell & Moring, Counsel to The Product Liability Alliance (TPLA) in testimony on May 20, 1986 before the Senate Committee on Commerce, Science and Transportation regarding federal product liability legislation. In his presentation, Professor Schwartz discussed instances in which courts had established liability for unknown risks, liability without defect, and liability for fear of future injury.[10] In a paper accompanying Professor Schwartz's testimony entitled, "The Hunt for Past Product Liability Claims Data: A Misplaced and Misleading Enterprise," a rather sobering prospect emerges: "If a court ever combines these rules, a person could recover tort damages even when there has been no fault, no defect, and no injury!"

In such a legal environment, it is impossible to predict the exact extent to which the notification this bill mandates will generate product liability lawsuits, but it is, we fear, wishful thinking to believe that the impact would be anything less than dramatic.

IV. THE HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987 WILL AGGREVATE THE INSURANCE CRISIS CONFRONTING BUSINESS GENERALLY AND SMALL BUSINESS IN PARTICULAR.

Members of this subcommittee are well aware that American business has for the past two years been the victim of a crisis in the affordability and availability of liability insurance unprecedented in its severity and scope. Horror stories abound which relate tales of massive increases in liability insurance premiums, severe reductions in coverage, combinations of both and, of course, non-renewals and the total inability of some companies to obtain coverage at any price.

As product sellers, wholesaler-distributors have been particularly hard hit in the product liability insurance market. The dramatic increases in product liability insurance premiums and reductions in coverage reported by NAW member companies over the past two years are the direct result of the collision between a disjointed and uncertain tort system with an insurance system that requires stability and predictibility in the rules that govern exposure to liability.

For the better part of the past decade, NAW has vigorously pursued uniform product liability law first at the state and, subsequently, at the federal level. The central purpose of our effort is to build a fair, balanced and stable legal environment in which wholesaler-distributors and their insurers will be able to accurately and objectively assess product liability risks and maintain an affordable insurance program.

To the extent that the worker notification mandated in the Act generates volumes of additional litigation, legal costs, and losses that cannot be objectively and accurately predicted, the difficult situation businesses

-- particulary smaller businesses -- currently face in the insurance market would be significantly aggrevated.

Moreover, there is every reason to believe that enactment of the Act would have a similar effect on the cost of the workers' compensation system. As previously discussed, NAW is deeply concerned that the Act would generate an explosion in claims to an extent which we cannot today predict. One thing is generally certain, however; that the premiums wholesaler-distributors and other employers will pay for workers' compensation will rise rather dramatically.

Finally, in a somewhat different vein, Mr. Chaiman, NAW members are concerned about the cost that would accrue to employers for providing to all notified employees the testing, evaluation and medical monitoring mandated by the Act. It seems clear that under this proposal, tens of thousands of individuals will be notified that they are at "high risk" of contracting a serious illness due to the presence of a dangerous substance in the workplace. While few will ever contract the specified disease, and fewer still will be able to show that the harm is in fact work-related, all will be entitled to employer-funded testing, evaluation, medical monitoring and counseling.

In addressing this very subject in connection with similar legislation introduced in the House of Representatives in the previous Congress (H.R. 1309, 99th Congress), the nine minority members who signed Minority Views to the Education and Labor Committee's report hit the nail right on the head:

> "The cost of providing for this coverage will substantially increase the cost of health care benefit plans ... it is doubtful such coverage will be made available to employers or their employees. In the case of an employer whose profit margin is small, it could be the deciding factor in a business permanently closing its doors."[11]

Given the seriousness of the debate surrounding the benefits that are likely to be derived from enactment of this bill, this seems an unacceptably high price for society to pay.

V. THE ANTI-DISCRIMINATION PROVISIONS OF THE BILL CREATE HURDLES THAT MOST WHOLESALER-DISTRIBUTORS WOULD FIND ENORMOUSLY COSTLY TO CLEAR.

The new category of employees created by the Act; i.e., employees who are members of a population at risk of disease, cannot "in any manner" be discriminated against because of that determination. Further, if it is medically determined that such an employee should transfer to another position, he or she would do so at no loss in pay, seniority, or benefits. For wholesaler-distributors and other smaller employers, this provision is of particular concern.

For example, this requirement is certain to have a significant and adverse effect on the cost and availability of group medical and life insurance policies that typically comprise a major part of the wholesaler-distributor's employee benefits package.

Second, with respect to job transfers, for smaller employers who do not have alternative positions available, the Act provides for protection against loss of pay, etc., for a full year. This transfer protection is at the cost of the employer and would include compensation for no work where there are no available alternative jobs.

Here, again, it is appropriate to observe that given the serious questions that have been raised concerning the practical benefits of this measure, the costs of this approach seem excessive to say the least.

VI. CONCLUSION

Mr. Chairman and members of the subcommittee, the central purpose of the High Risk Occupational Disease Notification and Prevention Act of 1987 is already being achieved under existing law in a manner that offers greater protection and benefit to American workers. Conversely, the legislation now pending before the subcommittee adds a high degree of complexity to an already complicated situation and would impose costs on American employers and businesses that is beyond estimation. Enactment of the bill will spark an explosion in workers' compensation claims and tort actions and fuel the fires of an already oppressive insurance crisis.

Therefore, the National Association of Wholesaler-Distributors opposes the High Risk Occupational Disease Notification and Prevention Act of 1987 and would respectfully urge you not to report it.

Thank you for your consideration of NAW's views.

FOOTNOTES

1. 29 CFR 1910.1200
2. 48 Fed. Reg. 53280 (1983)
3. 48 Fed. Reg. 53280 (1983)
4. 48 Fed Reg. 53327 (1983)
5. 48 Fed. Reg. 53280 (1983)
6. *United Steelworkers of America v. Auchter*, 763 F. 2d (3rd Cir. 1985)
7. 50 Fed. Reg. 48794 (1985)
8. McAteer, J. Davitt and Lawson, Dale, *Chemical Hazards: A Guide to the New Hazard Communication Standards*, Occupational Safety and Health Law Center, Pilgrim Press, p. 55-56.
9. Subcommittee on Labor of the Senate Labor and Human Resources Committee, Statement of Patrick R. Tyson, Acting Assistant Secretary of Labor for Occupational Safety and Health, May 15, 1986.
10. Senate Commerce, Science and Transportation Committee, Statement of Victor E. Schwartz, Esq., Crowell & Moring, May 20, 1986.
11. Committee on Education and Labor, U.S. House of Representatives, Report 99-691, p. 32.

(APPENDIX A)

National Wholesaler-Distributor Organizations Affiliated with the National Association of Wholesaler-Distributors

Air conditioning & Refrigeration Wholesalers
American Jewelry Marketing Association
American Machine Tool Distributors Association
American Supply Association
American Traffic Safety Services Association, Inc
American Veterinary Distributors Association
Appliance Parts Distributors Association, Inc
Associated Equipment Distributors
Association of Footwear Distributors
Association of Steel Distributors
Association of the Wall and Ceiling Industries International
Automotive Service Industry Association
Aviation Distributors & Manufacturers Association

Bearing Specialists Association
Beauty & Barber Supply Institute, Inc
Bicycle Wholesale Distributors Association, Inc
Biscuit & Cracker Distributors Association

Ceramic Tile Distributors Association
Copper & Brass Servicenter Association
Council for Periodical Distributors Association
Council of Wholesale Distributors
  National Kitchen & Bath Association

Door & Hardware Institute

Electrical Electronics Materials Distributors Assn
Explosive Distributors Association, Inc

Farm Equipment Wholesalers Association
Fire Suppression Systems Association
Fluid Power Distributors Association, Inc
Food Industries Suppliers Association
Foodservice Equipment Distributors Association

General Merchandise Distributors Council

Health Industry Distributors Association
Hobby Industry Association of America

Independent Medical Distributors Association
Institutional & Service Textile Distributors
  Association, Inc
International Sanitary Supply Association
Irrigation Association
International Truck Parts Association
Jewelry Industry Distributors Association

Machinery Dealers National Association
Material Handling Equipment Distributors Association
Monument Builders of North America Wholesale Div
Motorcycle Industry Council
Music Distributors Association

National American Wholesale Grocers' Association
National Appliance Parts Suppliers Association
National Association for Hose &
  Accessories Distributors
National Association of Aluminum Distributors
National Association of Chemical Distributors
National Association of Container Distributors
National Association of Decorative Fabric Distributors
National Association of Electrical Distributors
National Association of Fire Equipment Distributors
National Association of Floor Covering Distributors
National Association of Manufacturing Opticians
National Association of Marine Services, Inc
National Association of Meat Purveyors
National Association of Plastics Distributors
National Association of Service Merchandising
National Association of Sporting Goods Wholesalers
National Association of Textile & Apparel Distributors
National Association of Tobacco Distributors
National Association of Writing Instrument Distributors
National Beer Wholesalers Association
National Building Material Distributors Association
National Business Forms Association
National Candy Wholesalers Association
National Commercial Refrigeration Sales Association
National Electronic Distributors Association
National Fastener Distributors Association
National Food Distributors Association
National Frozen Food Association
National Grocers Association
National Independent Poultry and Food Distributors Association
National Industrial Belting Association
National Industrial Glove Distributors Association
National Lawn & Garden Distributors Association
National Locksmith Suppliers Association
National Marine Distributors Association
National Paint Distributors, Inc
National Paper Trade Association, Inc
National Plastercraft Association
National Sash & Door Jobbers Association
National School Supply & Equipment Association
National Solid Wastes Management Association
National & Southern Industrial Distributors Associations
National Spa and Pool Institute
National Truck Equipment Association
National Welding Supply Association
National Wheel & Rim Association
National Wholesale Druggists' Association
National Wholesale Furniture Association
National Wholesale Hardware Association
North American Heating & Airconditioning Wholesalers
North American Wholesale Lumber Association, Inc

Optical Laboratories Association
Outdoor Power Equipment Distributors Association

Pet Industry Distributors Association
Petroleum Equipment Institute
Petroleum Marketers Association of America
Power Transmission Distributors Association, Inc

Safety Equipment Distributors Association, Inc
Scaffold Industry Association
Security Equipment Industry Association
Shoe Service Institute of America
Specialty Tools & Fasteners Distributors Association
Spring Service Association
Steel Service Center Institute

Textile Care Allied Trades Association
Toy Wholesalers' Association of America

United Pesticide Formulators & Distributors Association

Video Software Dealers Association

Wallcovering Distributors Association
Warehouse Distributors Association for
  Leisure & Mobile Products
Water and Sewer Distributors Association
Wholesale Florists & Florist Suppliers of America
Wholesale Stationers' Association, Inc
Wine & Spirits Wholesalers of America, Inc
Woodworking Machinery Importers Association
Woodworking Machinery Distributors Association

NATIONAL ASSOCIATION OF WHOLESALER-DISTRIBUTORS
1725 K Street, N.W., Washington, D.C. 20006 • 202/872-0885

1/87

APPENDIX B

NATIONAL ASSOCIATION OF WHOLESALER-DISTRIBUTORS

1725 K Street
Washington, D.C.
202/872-0885

February 24, 1986

Docket Officer
Docket No. H-022 D
Room N 3670
Occupational Safety and
Health Administration
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Re: Hazard Communication; Advanced Notice of Proposed Rulemaking

Gentlemen:

The Occupational Safety and Health Administration (OSHA) has requested comments and information on expanding the scope of industries covered by the Hazard Communication Standard (HCS) which currently covers a segment of the manufacturing industry.

The National Association of Wholesaler-Distributors (NAW) is pleased to present its comments with respect to the proposed expansion of scope. NAW is a federation of 120 national wholesale distribution trade associations, 60 state and regional trade associations and over 7,000 individual wholesale distribution firms. In all, NAW represents approximately 45,000 wholesale distribution companies with 150,000 places of business nationwide. The wholesale distribution industry is a massive and rapidly growing part of the American economy and NAW is the national voice of wholesale distribution.

The membership of NAW is dominated by smaller businesses and is responsible for over 60 percent of the $1.4 trillion of merchandise which flows through wholesale channels annually. NAW members employ a comparable percentage, 3 million out of 5 million, of those who work in the wholesale trade. NAW members purchase from, and in other cases are suppliers to, manufacturing concerns operating in all states and the District of Columbia. The range of products sold by NAW members include those that can be considered hazardous and those that pose no hazard whatsoever.

In some instances, members sell and ship the product in its original containers while in other cases, the containers are broken down and the product is shipped in a different form or container. Under some circumstances, employees of NAW members may be exposed to materials considered to be hazardous while in others, there is no such exposure. Under other circumstances, employees of the customers of NAW members may be subject to exposure to materials considered to be hazardous which have been obtained from such NAW members. Various state laws dealing with right-to-know subject NAW member wholesaler-distributors to a wide range of coverage and compliance requirements.

Comments have been invited with respect to the question of expansion of coverage of the OSHA HCS. NAW is not convinced at this time that there is any evidence of undue risk to employees of wholesaler-distributors to establish a need for inclusion of the wholesale-distribution industry under the OSHA HCS. NAW also recognizes the need for a consistent approach to hazard communication and the serious threat to that consistency posed by a myriad of state rules, many of which have current application to wholesaler-distributors.

In addition to comments with respect to expansion, certain information has been requested in the form of responses to a series of questions posed in the advance notice of proposed rulemaking. Because of the diversity of membership of NAW, being composed of trade associations and wholesaler-distributors in various commodity lines, an NAW response to these specific quetions is not feasible. However, NAW does feel that general comments with respect to the question of expansion of coverage are necessary.

The HCS has been characterized as OSHA's most all-encompassing regulation. It affects more employers than any other OSHA regulation and requires a great deal of work on the part of affected employers in order to comply. OSHA has consistently taken the position that its current rule preempts state laws on the same subject.

In responding to an attack in court against the preemption rule, OSHA argued that preemption was necessary since a uniform standard would reduce the regulatory burden posed by varying state laws. The court agreed that the standard should preempt state laws within the manufacturing sector but did not decide whether state laws operating outside of the manufacturing sector were preempted.

The fact is that there are many state laws at the present time that are operating outside of the manufacturing sector. These laws have different standards of coverage and widely varying compliance requirements. This wide variety of state laws creates a potential compliance nightmare for the wholesale distribution industry. Thus, there is a strong need for federal OSHA preemption to eliminate the confusion and complexities that make compliance a practical impossibility under the varied and sundry state laws. Because wholesale distribution is already covered under most of these state laws and because there is an absolute need for certainty and uniformity in the application of hazard communication rules, NAW supports Federal preemption for sectors operating outside of the manufacturing sector.

Certain basic elements are an absolute necessity of any preemptive set of OSHA regulations. Such regulations must provide the requisite certainty and uniformity that would eliminate differences in application of coverage and obligations under the rule and all work necessary to implement programs in compliance with that rule can be accomplished without imposing of severe economic hardship on the newly covered industry segments.

NAW appreciates this opportunity to express its views on this important matter.

Respectfully yours,

James A. Anderson, Jr.
Director-Government-Relations

JAA:sh

RUBBER MANUFACTURERS ASSOCIATION
1400 K STREET N.W. • WASHINGTON D.C. 20005 • (202) 682-4826

OFFICE OF THE PRESIDENT

March 5, 1987

The Honorable Howard M. Metzenbaum
U.S. Senate
Washington, D.C. 20515

Dear Senator Metzenbaum:

The RMA is a national trade association representing approximately 200 companies engaged in the production of tires and other rubber goods. I am writing to voice concern over pending occupational disease notification legislation, S.79, which is before the Labor and Human Resources Subcommittee on Labor. It is the position of RMA that this legislation is unnecessary and inappropriate for the following reasons:

1) The OSHA Hazard Communication Standard sufficiently provides for notification to current employees about occupational hazards to which they are exposed and their potential effect on worker health. This Standard went into effect on May 25, 1986, and is the most comprehensive rule promulgated by OSHA. Having been in effect for only nine months, it should first be evaluated as to its effectiveness and improved, if necessary, before Congress creates an entirely new program. With regard to former employees, OSHA's Access to Employee Exposure to Medical Records (CFR 1910.20), which became effective August 21, 1980, requires employers to maintain and provide current and former employees access to records of employee exposure and records of medical surveillance.

2) OSHA inspections evaluate hazards and provide enforcement in those instances where employees are found to be at risk. In addition, NIOSH conducts routine health hazard evaluations which focus on employee hazards. Furthermore, employees and their representatives are made aware of these findings.

3) In addition to governmental programs, industry has discharged its responsibility by recognizing, controlling and eliminating potential employee exposure to occupational hazards. The risks for failing to do so are exemplified by the black lung benefits program, the asbestos litigation crisis, as well as spiraling health care and product liability costs.

4) Unnecessary legislation of this type would create an overlapping, unwieldy, expensive, new bureaucracy within the Department of Health and Human Services which could rival and clash with the Occupational Safety and Health Administration.

5) Methods to enact such legislation establish insufficient and unclear criteria for identifying employees at risk who should be notified. They are also premised on a greater technological feasibility and effectiveness from medical monitoring and screening than those procedures have been able to deliver. The bill's requirement that no fewer than 100,000 employees be notified each year is arbitrary and undermines any attempt to maintain a "statistically significant" determination of populations truly at risk and deserving of notification. Notifying workers incorrectly that they are at risk of contracting a disease would be unjustifiably distressing.

6) The cost of locating, notifying and counseling each affected worker, and of establishing at least one health center per state would be staggering.

7) The legislation as proposed would greatly increase the cost of health insurance and workers' compensation insurance, and it would serve as a catalyst for unnecessary employee lawsuits filed against employers. The impact of this liability on the already existing liability crisis would be enormous.

8) Overall, this legislation will have a significant anticompetitive impact upon the business sector, particularly at a time when we are searching for solutions to the trade imbalance problem.

RMA supports the belief that employees who are at risk of occupational disease should be informed so that preventive measures can be taken. This goal is achievable with existing programs to the extent that the adoption of S.79 is unnecessary. I urge you to consider all of these points carefully and oppose S.79 when it is considered by the Subcommittee.

Very truly yours,

Donald G. Brotzman

mrs
cc Senate Committee on Labor
and Human Resources

STATEMENT OF THE NATIONAL ASSOCIATION OF INDEPENDENT INSURERS

TO THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES SUBCOMMITTEE ON LABOR

REGARDING S.79

FEBRUARY 24, 1987

The National Association of Independent Insurers opposes S.79 for the following reasons:

1. The bill lacks adequate standards for identifying occupational health hazards.

2. It would undermine and displace the state workers' compensation system.

3. It would duplicate existing occupational safety and health programs.

My name is Sam Sorich, Assistant Vice President for Workers' Compensation, with the National Association of Independent Insurers (NAII), a trade association comprised of over 500 property and casualty insurance companies.

NAII believes in the concept of identifying and preventing illnesses among workers who are at risk of occupationally induced diseases. It is our opinion, however, that S.79 is not the proper means for implementing that concept. NAII firmly believes that the goals of identifying, notifying and treating workers who suffer from occupational diseases can be best achieved by the state workers' compensation system and the existing state and federal occupational safety and health laws and regulations.

S.79 lacks adequate standards for determining when notification is warranted.

S.79 charges the Risk Assessment Board with notifying employees exposed to an occupational health hazard, but the Board is given no valid standard for determining the existence of a hazard. According to Section 3 of the bill, the notification process may be triggered simply by "statistically significant evidence," which can be as meager as "one study conducted in accordance with established scientific principles." The relinquishment to the Board of total responsibility to determine the existence of a hazard without any reliable, valid standard conflicts with the bill's goal of notifying workers who may suffer from occupational diseases. If the Board is allowed to declare the existence of an occupational health hazard without any clear guidelines, there is surely a danger that employees with a legitimate need for notification will be neglected.

The risk of haphazard notification by the Board is compounded by the mandate in Section 4 of the bill that each year the Board must attempt to notify 300,000 employees, and in any case must notify 100,000 employees. This mandate compels the Board to find statistically significant evidence of occupational health hazards in order to meet the arbitrary numbers set out in the bill. If nothing else, the notification mandate in the bill is duplicitous. On one hand, the board is directed to use objective, scientific evidence to determine the existence of a health hazard. On the other hand, the Board is told, in effect, "In spite of what scientific examination discovers, you had better find some justification for notifying at least 100,000 employees each year."

The lack of adequate standards for identifying the existence of an occupational health hazard and the mandate to notify an arbitrary number of workers represent flawed scientific methodology and poor public policy. Moreover, these provisions raise serious ethical concerns. The notification that an employee may be afflicted with a disease can have devastating physical and emotional effects on the worker and his or her family. Basic ethical principles dictate that before subjecting workers and their families to this distress, there should be a solid foundation for believing that the worker is afflicted with an occupational disease. S.79 provides no assurance that this foundation will be established.

S.79 would undermine and displace the state workers' compensation system.

During the last decade, state workers' compensation laws have made great progress in recognizing and compensating occupational diseases. Today, state workers' compensation laws provide full coverage and fair benefits to occupational disease victims.

The progress that has been made in improving the state compensation laws would be thwarted by S.79. The levels of notification called for in the bill would, no doubt, result in a flood of filings for compensation benefits. The state compensation system can cope with legitimate claims for diseases arising out of and in the course of employment. But, the lack of standards for notification in S.79 would create a real risk that great numbers of employees who do not have compensable workers' compensation claims would nevertheless receive notifications. The notices themselves will encourage employees to file workers' compensation claims, even though many of these claims are not compensable. These filings will result in a substantial amount of litigation and will drain the resources of the state workers' compensation agencies.

There is a further danger that the notifications ordered by the Board will be used in workers' compensation and civil court proceedings. Section 10 of the bill attempts to preclude the direct use of notifications in other proceedings. We, however, believe that the language in Section 10 is unsatisfactory. The language in Section 10 would not necessarily prohibit the indirect use of notification information in workers' compensation cases and other legal actions. Without tighter language on the use of notifications and notification information, insurers and employers will be at a great disadvantage in defending workers' compensation and liability cases.

We must also express concern about the effect that the benefit reduction prohibition in Section 9 of the bill may have on workers' compensation rehabilitation efforts. We are certainly opposed to unfair discrimination against occupationally diseased employees. However, we are concerned that the dictate by the Secretary of Health and Human Services that an employee must be transferred to a certain job may subvert valuable rehabilitation activities. Workers compensation rehabilitation is most effective when it is regulated by the state workers' compensation agency. Any federal safeguards against discrimination should be sensitive to this fact.

NAII believes that employees and their employers are best served by the state workers' compensation system. No matter how well meaning the goal of notifying diseased employees may be, we are convinced that a federal program such as that provided for in S.79 will be used by the advocates of federal control as a major step toward a federalization of workers' compensation.

S.79 is redundant and wasteful.

S.79's threat to the state workers' compensation system is needless because most of the bill's goals can be achieved through existing occupational safety and health programs. The health centers to be established pursuant to Section 7 of the bill appear to duplicate the functions of NIOSH's educational centers. OSHA's Access to Employee Exposure and Medical Records Rule already requires employers to inform employees of the existence, location, and availability of medical records and to inform them of their rights to access to those records. Most importantly, OSHA's Hazard Communication Standard does a better job of notifying current employees than the notification program proposed in S.79.

It would be wasteful to duplicate these existing programs. The accomplishments and potential of these programs need to be thoroughly examined before we race headlong into another costly federal program.

There are other problems in S.79.

Other provisions in S.79 deserve attention. Section 4 of the bill provides that the five members of the Risk Assessment Board are to be Public Health Service employees. The Board could be counted on to make more responsible decisions if it had a broader representation. Representatives of employers and insurers would seem to be appropriate additions.

Section 5 of the bill contemplates a program of individual notification that may simply be impossible to achieve.

The bill places the Risk Assessment Board under the Department of Health and Human Services. Given the experience and expertise of the Department of Labor in occupational health matters, that Department would seem to be a more appropriate location for the Board.

We cannot become involved in remedying these somewhat narrow problems in S.79 until the fundamental problems in the bill are addressed. NAII must continue to oppose S.79 until the issues of inadequate standards, the detrimental effect on state workers' compensation systems and the duplication of existing safety and health programs are resolved.

Statement of John F. Hall, American Wood Preservers Institute On S. 79, The "HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987"

Before the Subcommittee on Labor of the
Senate Committee on Labor and Human Resources

March 11, 1987

The American Wood Preservers Institute (AWPI), I would like to present its concerns with S. 79, the proposed "High Risk Occupational Disease Notification and Prevention Act of 1987."

The American Wood Preservers Institute is a national organization representing the wood preserving industry on federal environmental issues. AWPI's member companies produce the wood preserving pesticides and pressure treat wood products to assure long-term serviceability in adverse situations.

INTRODUCTION

The American Wood Preservers Institute supports the basic goal of the proposed legislation -- the concept that employees have the right to know about hazards of chemicals to which they are exposed and how to protect themselves. AWPI also believes that employees should know if they are at risk of contracting an occupational disease, how great the actual risk is, and to be informed of the signs and symptoms of the onset of disease.

AWPI does not believe that S. 79 will achieve these stated goals. In fact, this legislation will have adverse effects that will outweigh any of its beneficial results. It will institute a new, costly program that is unnecessary to achieve the goals above.

The Institute appreciates the various improvements made by Senator Metzenbaum in S. 79 over a similar bill introduced in the 99th Congress. However, the program that would be instituted is still duplicative and therefore represents poor public policy.

S. 79 WOULD INSTITUTE A PROGRAM THAT WOULD BE DUPLICATIVE

The wood preserving industry opposes S. 79 because it is not needed and is duplicative of legislation that has already been enacted.

OSHA's Hazard Communication Standard already requires employers to inform employees of hazards in the workplace and their potential health effects. The Standard has only been in effect since May 1986. The effectiveness of this program should be assessed before Congress creates an entirely new program.

This type of notification legislation would create an overlapping and expensive new bureaucracy in the Department of Health and Human Services (HHS) not only to identify workplace hazards but also to identify current and former employees who are or were at risk -- all without input from other public agencies or the private sector. Important input from OSHA could not be considered. Legislation such as this Act would be costly to taxpayers because of the massive, overlapping and contradictory "new OSHA" bureaucracy it would create.

The process contained in this legislation for notifying individuals would be lengthy and tedious. This mechanism also has many inherent problems such as the potential for false notification and is a very real potential for litigation.

S. 79 DOES NOT REDUCE WORKER EXPOSURE TO POTENTIALLY HARMFUL SUBSTANCES

It is important to protect workers from potentially harmful toxic substances in the workplace. However, the legislation that has been introduced does nothing to reduce and eventually eliminate death and disability caused by diseases resulting from exposures to toxic substances and processes in the workplace. There are no provisions in the legislation, in areas such as the lowering of permissible exposure levels (PELs), for potentially hazardous substances or for worker training.

S. 79 COULD RESULT IN AN EXPLOSION OF LIABILITY

Individual notification is an integral part of the mechanisms of S. 79. Notification, as proposed by the bill, will cause many employees to file tort and worker compensation actions against their employers. If the legislation contains no solution to this litigation generating feature, business will face billions of dollars in legal liabilities, a cost ultimately born by employees and consumers.

BETTER APPROACHES TO EMPLOYEE NOTIFICATION CAN BE DEVELOPED

AWPI urges the Committee to consider a better approach to achieving the goals of S. 79. Existing "right to know laws" could be amended to establish one clear authority for the issue.

All "right to know" legislation, including any product from High Risk Occupational Disease Notification, should be melded into one statute. This would simplify reporting requirements and result in a program that would confer a higher level of protection of human health and the environment.

The goals of High Risk Occupational Disease legislation and other right-to-know statutes would not be altered by their combination. Only duplication and torturous notification processes within unconnected federal agencies would be eliminated. In fact, an umbrella standard would probably ensure that more knowledge about workplace hazards was disseminated to the public, in contrast to piecemeal information in response to a plethora of individual laws.

Many business oriented associations such as the National Association of Manufacturers have advocated the expansion of the Hazard Communication Standard, 29 C.F.R. Sec 1910.1200 (1986) to cover additional groups of employees. Current employees are already being notified under Hazard Communication.

A use of the Hazard Communication Standard for this type of notification would minimize duplication of efforts. It is possible that industry could notify retirees and the government could undertake the responsibility of notifying other past employees. Many companies, especially those in the chemical industry, already have risk assessment procedures and should be permitted to continue with their own programs, with some oversight from a broad-based scientific advisory group.

In the Superfund Amendment and Reauthorization Act (SARA) signed into law in November of 1986, the Congress codified the Material Safety Data Sheets required by the Hazard Communication Standards. This example demonstrates that existing mechanisms can be used rather than creating new ones. AWPI supports the concept of working within the existing regulatory framework rather than creating an entirely new regulatory scheme.

CONCLUSION

The American Wood Preserving Institute supports the goal of notification of present and future employees of hazards and risks of exposure to chemicals is a valid goal. However, AWPI believes that existing law that requires manufacturers to perform this function is sufficient for current employees while notification of past employees could be done within the existing framework already in place.

The Institute strongly urges Congress not to pursue the approach set forth in S. 79 but instead to examine ways of using current statutes to achieve these notification goals.

BEFORE THE UNITED STATES SENATE COMMITTEE
ON
LABOR AND HUMAN RESOURCES
SUBCOMMITTEE ON LABOR

COMMENTS ON S. 79
THE HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987

Submitted by:

The American Association of
Occupational Health Nurses
50 Lenox Pointe
Atlanta, Georgia 30324

Date: March 2, 1987

The Board of Directors of the American Association of Occupational Health Nurses has voted unanimously to support S. 79 - the High Risk Occupational Disease Notification and Prevention Act of 1987.

We applaud the bill's goal to establish a federal program to identify, notify, counsel and monitor workers at high risk of occupational disease.

We have analyzed the bill and offer the following suggestions for strengthening what we expect to be one of the most significant pieces of legislation produced by the 100th Congress.

Section 3. Definitions

We continue to question the use of the word "medical" in connection with monitoring and surveillance. The term implies that these important activities are performed exclusively by physicians.

Last year, the Senate Appropriations Subcommittee, then-chaired by Sen. Weicker, acknowledged that "more than one-half of our nation's work settings rely on nurses to be responsible for the medical surveillance which is required by OSHA."

To reflect the significant role played by occupational health nurses in surveillance and monitoring and to indicate the broad range of health and safety issues covered by the surveillance and monitoring process, we strongly urge you to change the language of the bill to include the terms health surveillance and health monitoring.

Section 4. Risk Assessment Board

With respect to the proposed Risk Assessment Board, we applaud the inclusion of an occupational health nurse as one of the health professionals represented on the board.

However, we question whether there is an adequate supply of career or commissioned public health service occupational health nurses from which to draw for the Risk Assessment Board. We recommend expanding representation outside the public health service to include a combination of Public Health Service Employees and qualified health professionals from the private sector.

Section 7. Occupational and Environmental Health Center

With respect to the functions of the proposed occupational and environmental health centers, we recommend that the centers be capable of providing diagnosis, treatment, health monitoring and support services for employees notified under Section 5 of the bill.

We believe that the term "support services" (which includes family services) is more appropriate because it also includes financial, psychological, medical, legal and career development services.

Section 8. Reserach, Training and Education

We agree that courses of study on occupational disease should be offered by institutions of higher learning. However, we believe that the recommendation should not be restricted to schools of medicine.

Occupational health nurses are the primary providers of on-the-job health care. As Levy and Wegman point out in Occupational Health:

"Occupational health nurses are central to the activities of almost all occupational health and safety programs; they play key roles in large workplaces and are often the predominant health care providers for small companies. Nurses can and do perform many activities and assume responsibilities beyond the specific role of primary nursing care. These include health promotion and disease prevention, hazard surveillance and control, review and control of lost time and medical care costs, ensuring compliance with state and federal occupational safety and health regulations, and administration of health insurance programs, records, and reporting systems."

As a result, we recommend that S. 79 contain language broadening the section that addresses the issue of federal financial assistance to schools of medicine offering courses of study on occupational disease. We believe that the same provisions should apply to colleges of nursing.

We agree that research, training and education are important in developing improved methods of identifying and monitoring occupational hazards and diseases.

However, since prevention is a key factor in controlling and reducing the incidence of occupational disease, we recommend including research of substances and processes before they are introduced into the workplace.

Conclusion

We wish to reiterate our support for S. 79 and express our confidence that, with the modifications that we have suggested, the bill will make a major contribution to protecting the health and safety of America's workers.

nsa NATIONAL STONE ASSOCIATION
1415 ELLIOT PLACE, N.W. • WASHINGTON, D.C. 20007 • 202-342-1100

Comment for the Record
to the
Subcommittee on Labor
of the
Labor & Human Resources Committee
U.S. Senate
on S.79
High Risk Occupational Disease Notification
and Prevention Act of 1987

Submitted March 9, 1987
by the
National Stone Association

The National Stone Association (NSA) appreciates the opportunity offered by the Chairman of the Senate Subcommittee on Labor to submit written comment for the record on S.79, the High Risk Occupational Disease Notification and Prevention Act of 1987.

The National Stone Association is the trade association representing over 400 companies in the crushed stone industry throughout the United States. Approximately 1.1 billion tons of crushed stone was produced in the United States in 1986 - with stone quarried in all states except Delaware.

NSA and the crushed stone industry support the major objectives of S.79. NSA also agrees with the comment by the Chairman of the Subcommittee in his opening statement at the February 24, 1987 public hearing when he cited the need for law in this area which is fair to employers as well as workers and one that can be enforced effectively. NSA has examined S.79 and S.638 (introduced on March 3, 1987 in the Senate) as well as the occupational disease notification bills introduced in the 99th Congress. It is obvious that each bill introduced has significantly improved upon the bills which preceded it. Undoubtedly, this improvement was the result of facts brought to the Subcommittee during the hearing process.

NSA respectfully submits this written comment for the record in the hope that it, too, will contribute constructively to the Subcommittee's search for the best legislative course. NSA would urge the Subcommittee to review and consider the number of bills passed by the Congress and the number of regulatory agency mandates issued in recent years before proceeding further with S. 79.

Significant progress has been realized in the identification of hazardous working conditions, in the development of environmental and workplace controls of individual exposures and in the detection, understanding and treatment of physical effects resulting from exposures.

NSA suggests to the Subcommittee that the Agency for Toxic Substances and Disease Registry (ATSDR) which was established under the Superfund, or Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA) and the Superfund Amendment and Reauthorization Act (SARA) of 1986 is already fully adequate to address effectively the purpose stated in Section 2 (b) of S.79. ATSDR is charged under CERCLA to "...establish and maintain a national registry of persons [occupationally and non-occupationally] exposed to toxic substances." This national registry is to include current and past exposed persons.

ATSDR will hold a National Workshop on a National Registry of Persons Exposed to Hazardous Substances at the Westin Peachtree Hotel in Atlanta, Georgia March 23-24, 1987. ATSDR and the Centers for Disease Control (both of which are under the Health and Human Services Department of the federal government) have produced a working draft of a National Registry Proposal. NSA believes that this working draft, issued in January 1987 by ATSDR and CDC, would serve the purposes of Occupational Risk Notification without the confusion and burden of a new federal law. A copy of the Working Draft, National Registry Proposal, is appended to these comments.

Stone Quarries are regulated in safety and health matters under the Federal Mine Safety and Health Act of 1977. Section 101 of this act relates to Mandatory Safety & Health Standards. Under Section 101(a)(1), the Secretary of Health & Human Services, the National Institute of Occupational Safety and Health and State or political subdivisions provide information and recommendations for new standards to the Secretary of Labor. This information includes the results of research, demonstrations and experiments.

The quarrying industry is currently experiencing careful evaluation of potential health risks through NIOSH's National Occupational Health Survey of Mining (NOHSM). This five year study of over 900 mines including a representative number of quarries will provide an in-depth record and analysis of the potential health hazards found in various types of mines. NIOSH began this study several years ago under authority granted to the Secretary of Health and Human Services by Section 100(a)(6)(B) of the Federal Mine Health and Safety Act of 1977. Also Section 101(a)(7) of the same act requires that standards ..."shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that miners are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such mandatory standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring miner exposure at such locations and intervals, and in such manner so as to assure the maximum protection of miners. In addition, where appropriate, any such mandatory standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the operator at his cost, to miners exposed to such hazards in order to most effectively determine whether the health of such miners is adversely affected by such exposure. Where appropriate, the mandatory standard shall provide that where a determination is made that a miner may suffer material impairment of health or functional capacity by reason of exposure to the hazard covered by such mandatory standard, that miner shall be removed from such exposure and reassigned. Any miner transferred as a result of such exposure shall continue to receive compensation for such work at no less than the regular rate of pay for miners in the classification such miner held immediately prior to his transfer."

Because of these strong pronouncements in the Federal Mine Safety and Health Act of 1977 the attention of the crushed stone industry has been focused on occupational illness prevention for a long time. NSA member companies already are communicating effectively and conscientiously with their employees about occupational health risks. Another law, such as S.79, which would create new agencies and new burdens is not necessary. Legislative mandates already exist and agencies to do the necessary job already exist. Federal agencies such as MSHA, OSHA, NIOSH, ATSDR and CDC are working effectively now to eliminate occupational disease wherever possible.

Most of NSA's member companies are small businesses. They and their workers look to paperwork reduction as a way to reduce costs, continue operating profitably and enhance job opportunity.

New laws establish new agencies, new legal requirements, new records and reports and other administrative burdens upon the medical community, the Department of Health and Human Services and the national economy.

NSA urges the Congress not to make the important task of worker protection from occupational health risks more cumbersome or more expensive than it need be.

The foregoing comments represent NSA's basic recommendation to the Subcommittee on Labor. In the interest of a complete, fully constructive statement, the following comments, directed specifically at S.79, are respectfully made. NSA has noted that others who testified before the Subcommittee have expressed views similar to those following.

1. Definitions - Section 3

   a. "Occupational Health Hazard" - This broad definition could cover agents, processes or procedures and relate to acute or chronic health effects which "may" occur among "exposed employees." "Exposed employees" is not defined and the use of the word "may" could result in imaginative findings. This definition also speaks to "statistically significant evidence based on at least one study conducted in accordance with established scientific principles." This quote from the definition of "Occupational Health Hazard" begs for inaccurate extrapolation of the results from tests on animals to humans. Unless studies such as animal or tissue studies are followed up by well-planned epidemiological studies on a statistically significant population of workers, they should not be allowed as a basis for determination of risk to an occupational health hazard - and certainly not as the sole basis for notification.

b. "Population at Risk of Disease" - Before such a population can be identified with an expectation of accuracy, there needs to be a definite description of exposure to a toxic agent or substance. Without a toxic agent or substance plus a demonstrated degree of overexposure, there is no hazard. Further, protective equipment or clothing or environmental control equipment may vary widely from one, otherwise similar, occupational site to another. An employer who is doing an excellent job of protecting his employees' health could be determined unfairly to employ a "population at risk." Workers not at risk, and their families, could receive false notification subjecting them unfairly to emotional stress and unjustified fear for their health and well-being.

2. Risk Assessment Board - Section 4
   a. This board would be redundant to other governmental entities already in existence under the Secretary of Health and Human Services.
   b. If established, the Risk Assessment Board should include epidemiologists, toxicologists, medical specialists and industrial hygienists among its members with peer review by similar professionals outside the government.
   c. A Risk Assessment Board should be required to operate under regulations established through standard regulatory procedures by the Secretary of Health and Human Services
   d. The Board procedures should be governed by the Administrative Procedure Act (APA) and judicial review should not be required in United States Court of Appeals until after APA appeal to the Secretary is allowed.
   e. Establishment of a notification minimum annual quota of 100,000 employees and the arbitrary establishment of specified numbers of days between publication of

proposed determinations by the Board, public comment, public hearings and final agency action virtually would eliminate valid scientific rebuttal of a Board finding. Even the exceptional circumstance exemption of only 150 days maximum is insufficient.

We appreciate the opportunity to present these reconnendations and trust they will be given due consideration in your final deliberations.

Respectfully submitted

Robert G Bartlett

Robert G. Bartlett, P.E.
President
National Stone Association

RGB/cvc

913

Tenneco Inc

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Edward J. Bernacki, M.D.
Vice President
Health, Environmental Medicine
and Safety

March 9, 1987

Senator Metzenbaum
United States Senate
Washington, D.C. 20510

Dear Senator Metzenbaum:

Re: Senate Bill 79

Tenneco appreciates this opportunity to submit comments on Senate Bill 79, the "High Risk Occupational Disease Notification and Prevention Act of 1987." Tenneco has enjoyed a fine reputation for its concern for employee health and welcomes circumstances that may lead to better employee health through information and medical care. Consequently, we applaud the Senate's goal in this bill of identifying and preventing illness and death of workers. We have the following suggestions, arranged for your convenience by sections of the bill, rather than by order of importance, to improve the chances of obtaining this goal by maximizing the effectiveness of this legislation.

General Comments

Tenneco wishes to express three general concerns about this legislation. First, early detection and treatment are effective in controlling only a few diseases; therefore, the goal to reduce the cost of medical care in America through preventive measures is unrealistic. This is compounded by the fact that there is no valid method of screening for many diseases and, in those few cases in which screening is acceptable, it is often not possible to significantly alter the course of the disease.

Second, this type of legislation, if not carefully constructed, could lead to unnecessarily alarming employees by notifications of circumstances that do not bear a rational relationship to actual risk. Senate Bill 79 adequately maintains the needed balance between actual risk and notification. The final form of this legislation needs to maintain that perspective so that the impact of warranted notifications are not diluted by those that are not sufficiently related to actual risk.

Finally, we are concerned that this legislation will generate significant economic burden for the economy by providing the basis for increased litigation. For example, numerous lawsuits could result in which the plaintiff has no disease or injury. We recommend that Congress consider this serious economic impact and place a limitation on liability by specifically providing that the resulting Act cannot be used as the basis for lawsuits in the absence of a manifested disease.

Definitions

Section 3(7) Strikeout "(based on at least one study conducted in accordance with established scientific principles)...." A single positive study is not sufficient to establish the relative risk of an entire population of potentially exposed employees. The Risk Assessment Board should base their decision for notification on all available data and not be hampered by a requirement to consider a single positive study when other studies of similar data may have yielded conclusions that there is no increased risk of disease.

Section 3(9) Replace "comparable to at least one study referred to in paragraph (7)." with "that would create significant increased risk of disease in exposed employees." The intensity and duration of exposure to hazardous materials in the workplace varies considerably from industry to industry, plant to plant, and within a plant. Because of this variation and the principles of dose-response, it is important that employees understand and be informed of relative risks based on their own exposure experience.

Risk Assessment Board

Section 4(a)(2) We recommend that this section read:

> Membership - The Board shall consist of twelve members representing the following scientific disciplines: occupational medicine, toxicology, industrial hygiene, epidemiology and occupational nursing. The Secretary shall designate one industrial representative and one Academic or Public Health Service representative for each discipline.

This bill's purpose is the notification of employees who are or have been exposed to hazardous materials in the workplace. Scientists who work with employees in the relevant work environments have knowledge, experience, and insight in employee exposures, which is essential for proper identification of populations at risk.

Section 4(b)(1)(A) Add the following:

(iv) Only human epidemiology data shall be used to identify populations at risk. The Assessment Board shall use the NIOSH guidelines developed by its Board of Scientific Counselors Subcommittee on Individual Worker Notification to determine the scientific credibility of epidemiology studies.

(v) Consider other medical health and epidemiological principles including consistency of associations, specificity of associations, strength of associations, dose-response relationship, biological plausibility, temporal relationships, statistical significance, magnitude of attributable risk, and the consequence of notifying a population at risk; and

(vi) consider all available scientific literature, evaluate the scientific credibility of the data and develop a consensus opinion as to whether the substance poses a risk to employees who are exposed. From this data, the Board shall assess the relative risk to an employee based on the intensity and the duration of his exposure.

Section 4(b)(2)(A) Change "or animal and laboratory studies" to "and animal and laboratory studies."

Section 4(b)(3)(C) This section should be removed from the bill. It assumes, prior to the determination of the Board, that at least 100,000 employees are currently experiencing an increased risk of disease.

Section 4(c)(2)(C) Change the written comment period to 90 days and change the hearing date to 60 days. 45 days for comment and 30 days for hearing is insufficient time for interested parties to adequately respond.

Employee Notification and Counseling

Section 5(b)(4) - Add "(G) The relative risk that an employee may experience based on his/her own intensity and duration of exposure."

Section 5(g)(3) provides for judicial action, setting aside Board determinations under four listed conditions. Those conditions do not include the possibility of Board error. Consequently, we recommend the addition of the following:

(E) Erroneous when all scientific data is considered.

Means of Employee Notification

Section 6(b)(2)(A) - Replace this section with the following:

The Secretary shall provide the contents of notification, as specified in Section 5(b), to employers. Employers shall determine the intensity and duration of exposure to their employees. This exposure information shall be provided to each employee in addition to the information described in Section 5(b). The employer should be responsible for notification of current employees and previous employees for which the employer has a current address.

Section 6(c)(1) - Add (3):

In the event that an employer is unable to notify a previous employee, the name, social security number, and exposure information shall be submitted to the Secretary and the Secretary shall be responsible for notification of these employees. The Secretary shall notify all former employees for which the employer does not have a current address by means of publication or the use of Social Security or Internal Revenue Service address files.

Section 6(d)(2) - Strike this section from the bill. The OSHA Hazard Communication Standard requires that employers not only provide material safety data sheets, but train their employees on the hazards of materials for which they are exposed. Because this training and exchange of information is required under the Hazard Communication Standard, we believe that this section is a redundant requirement and unnecessary.

Employee Testing; Discrimination Against Employees

Section 9(c) - The medical transfer provisions should require that current workplace conditions be considered when determining if an employee should be transferred. The workplace conditions may have changed significantly since the possible disease-initiating event occurred. Also tranfers should only be required when there is sufficient evidence that remaining in the "exposed job" would affect the diagnosed condition.

In the event that it is determined that the workplace exposure would affect the diagnosed condition, the employer should have the option of transferring the employee to a non-exposed job or modifying the workplace either by engineering or administrative controls or by providing personal protective equipment. Allowing the employer to reduce workplace exposure would provide the needed element of prevention which is not adequately addressed in the bill.

Subject of Federal Agency Studies

Section 12(a) - Replace this section with the following:

> Each Federal Agency that conducts epidemiologic studies on occupational disease initiated after the effective date of this Act shall submit to the Board the results of these studies. The Board shall utilize the criteria as defined in Section 4(b) and evaluate the study in light of other available data to determine if there is sufficient evidence to warrant notification.

Section 12(b) - Based on the recommended change in 12(a), this section should be deleted.

Tenneco Inc. appreciates this opportunity to comment on Senate Bill 79. If we can provide any information or assistance, please contact me at (713) 757-5591.

Sincerely,

E. J. Bernacki, M.D.
Vice President
Health, Environmental Medicine
and Safety

EJB:JH:ra
1159C

Associated Builders and Contractors, Inc.

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The Associated Builders and Contractors on behalf of 19,000 general contractors, subcontractors, suppliers and associated firms operating under the Merit Shop management philosophy appreciates the opportunity to comment on S.79, The High Risk Occupational Disease Notification and Prevention Act of 1987. Briefly stated, the Merit Shop philosophy is the free enterprise system at work on the construction jobsite -- a business climate in which any firm may work with another, regardless of labor affiliations. Today, Merit Shop firms are performing 75% of our nation's construction.

Our members, operating in a labor-intensive industry, know the value of a good and available workforce. Our members are active on the jobsite training employees in safety and health awareness. Because of the mutual dependency between employers and employees to maximize efforts and minimize costs, ABC firms are greatly concerned with occupational hazards affecting its workforce.

S.79 requires the notification of workers who are at risk of occupational disease and establishing a system for the identification and prevention of illness and death. ABC believes in preventive measures for the construction worker. These measures include appropriate training and education programs, use of material data sheets, and adequate protection from known harmful substances. ABC applauds the efforts of the 100th Congress in its efforts to protect the American workforce.

However an analysis S.79 shows that the bill is duplicative of existing law and regulation, misplaces emphasis on after-the-fact damage, creates exorbitant additional costs for businesses and will stifle the ability of labor-intensive industries, such as construction, to compete.

S.79 does not achieve its goal of worker protection and occupational disease prevention. Instead, the Act has the potential of destroying the small business entity and creating a nightmare of adjudication ending the tort reform movement.

ABC members have particular concerns. With a unique workforce and complex jobsite activity, it is already difficult for our members to adhere to current regulatory and legislative requirements. Most construction contractors will not be equipped either administratively or financially to deal with another layer of bureaucracy.

This legislation is particularly ill-suited for the construction industry. With previous legislative and regulatory requirements already being imposed, duplicative, costly and burdensome requirements would be forced on employers. The industry must already comply with federally-imposed OSHA requirements which provide exposure information to workers. The Employee Exposure and Medical Records Rule has been in effect since August 1980. The Access Rule contains a specific provision that employers must inform employees of the existence, location, and availability of medical records and must also inform them of their rights of access to those records. The Access Rule also grants former employees the right of access to these medical records.

OSHA also has twenty-two health standards that mandate medical surveillance at no cost to employees and OSHA must address the issue of medical monitoring in every new health standard it promulgates. The OSHA Act grants the National Institute for Occupational Safety and Health the authority and the responsibility to engage in establishing occupational and environmental health centers to conduct research on job-related disease, a specific provision of S. 79. The Institute has already established guidelines for notification of employees clearly identified as "at risk" in its studies.

OSHA has also promulgated the Hazard Communication Standard, 29 C.F.R. Sec. 1910.1200 (1986) which is shortly expected to apply to the construction industry. This Standard requires manufacturers (and soon construction) to evaluate every substance to determine whether there are possible adverse health effects from exposure to the substance. This is the most comprehensive regulation promulgated since the passage of the Occupational Safety and Health Act itself. Under the Standard, companies must develop a comprehensive material safety data sheet (MSDS) which must report the existence of even one study which demonstrates a harmful effect. In addition, containers must be labeled with the identity and hazard presented by the substance. Every employee who has any likelihood of being exposed to a hazardous substance must receive specific training through the employer's hazard communication program and must have access to relevant material safety data sheets. The employer must provide additional training each time a new hazard is introduced into the workplace and update the material safety data sheet each time new relevant information is learned about the substance.

In addition, at least forty-three states and jurisdictions have implemented worker "right-to-know" legislation or regulations which do apply now to construction. ABC and the industry have worked closely with the Occupational Safety and Health Administration in identifying, monitoring and correcting health and safety hazards on the jobsite. Mandated by law, there is a 12 member Construction Advisory Committee on Safety and Health in Construction. OSHA has recognized the complexity of the construction industry and has a Special Assistant for Construction as part of its administrative organization.

An understanding of the unique nature of the construction workforce is essential to understanding our difficulty with this legislation. Construction operates in a small business climate with a highly, labor-intensive and transient workforce with constantly changing jobsites. Workers are hired to perform jobs reflecting their specific skills. The effect of this manpower practice may cause a construction company to experience a 50-60% or higher turnover in its workforce over the course of a year. In some companies, it could be 200-500%. As projects reach various levels of completion, labor and skilled craftsmen are used and then laid off as necessary. It is possible for a single construction worker to work at a different location, for a different project, for a different employer, with different materials every single week. In addition, it is very common for one employer to hire and lay off the same employee four or five times a year, as scheduling demands. The employee may also work for different contractors on a project, particularly if he is a laborer and not a skilled craftsman.

Further, ABC's member companies do business on jobsites that could involve as many as 100 speciality subcontractors working for a general contractor. The number of specialty contractors on a jobsite at any one time varies due to the type of construction project, the weather, and the work schedules of other contractors. Like the workers in their companies, these subcontractors are extremely transient. They enter and leave jobsites quickly as the need for their particular function is met.

Because of the unusual type of work activity found in the construction business, it is near impossible for the average construction contractor to work with the requirements of this legislation -- particularly the notification requirement. There is no way for the contractor to protect himself from misguided and false claims of toxic exposure. Because of constant movement on the jobsite itself, it is near impossible to notify the employee of all dangers and near impossible to determine if the employee may have been substantially exposed to a toxic substance. Employers must rely on the responsibility of the employee to adhere to specific and intensive levels of safety and health training.

Both OSHA and the United States Court of Appeals for the District of Columbia Circuit have long recognized the uniqueness of the construction workforce and its problem in dealing with toxic exposure. For example, the Court approved OSHA's determination to exempt construction from the standard on inorganic lead. The Court determined that construction workers are exposed to toxic substances, if at all, only for very brief periods. Their work often requires movement from place to place on the jobsite.

Another consideration of the construction industry's requirements are the environmental effects. The Court of Appeals agreed with OSHA's determination that "As a worker moves from place to place -- frequently in outdoor workplaces where the weather poses an extreme variable -- environmental monitoring becomes irrelevant to his health. (See United Steelworkers of America, AFL-CIO v. Donovan, F.2d, 8 BNA OSHC 1810, 1900 (1980))

Studies done in 1984 by the Bureau of Labor Statistics report that only 7% of recordable occupational illness by category are disorders due to physical agents while 34% are skin diseases and 28% are disorders due to repeated trauma, i.e. hearing loss or a nerve disorder of the wrist. In the same study, our industry had an incidence rate of 16.3 cases per 10,000 full time workers as compared to the food industry which had 306.7 cases. However, even this industry recorded high incidence levels in the category defined as "disorders associated with repeated trauma." Statistics of workman compensation claims indicate that health-related injuries/illnesses account for only 1.5% of all claims. The majority of these occupational illnesses are skin lesions caused by improper handling of tools and materials. While we are aware that health hazards do occur in the workplace, these figures suggest more emphasis on training such as a Hazard Communication Standard or other standards currently required.

ABC members have always been encouraged to provide extensive training for both safety and health hazards. A "proactive" approach is encouraged, rather than a "reactive" mode which we believe S.79 to be. OSHA's Hazard Communication Standard is a type of "proactive" vehicle which allows employers to work with employees in the prevention of an occupational disease. If the employer knows that a chemical or mixture is toxic, then the employee should be told and taught how to handle the material safely. But then, it is up to the employee to take responsibility for their safety and health.

In conclusion, ABC once again applauds the Senate for their concern about the American workforce. However, S.79 is not the appropriate vehicle to address their needs. Many of the procedures are already enforced by OSHA and research is continually conducted by the National Institute for Occupational Safety and Health. These standards are appropriate and have been adapted for and by the construction industry. Industry representatives including labor are working in close liaison with OSHA and NIOSH. Pending standards are already on OSHA's drawing board.

ABC members, like others in the construction industry want to work cooperatively with OSHA and NIOSH to protect its most valuable commodity -- the workforce. However, costly and burdensome legislation will only serve to the workers' disadvantage. Cutbacks, layoffs and discrimination will happen if contractors must add another layer of bureaucracy to their already burdensome recordkeeping.

If Congress is concerned that OSHA and NIOSH are not doing the job intended by the original legislation enacted to create this enforcement, it appears that action should be taken to enforce the law, not create additional layers of bureaucracy, recordkeeping and costs to be borne by taxpayers and business alike.

With other existing alternatives in existence and the economic burden that this legislation would impose on the construction contractor, ABC opposes this duplicative legislation.

STATEMENT FOR THE RECORD

SUBMITTED BY

THE STANDARD OIL COMPANY

"HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987" (S. 79)

Overview/Position

The Standard Oil Company appreciates the opportunity to present our comments on the "High Risk Occupational Disease Notification and Prevention Act of 1987" (S. 79). Standard Oil is an Ohio corporation engaged in a broad range of oil and gas, natural resource, chemical and industrial product businesses, employing approximately 40,000 people.

The Standard Oil Company strongly supports the goal of protecting workers and preventing occupational disease. Our companies are in compliance with OSHA workplace standards; including the Hazard Communication Standard and the medical surveillance programs of the individual OSHA standards. Employees potentially exposed to agents for which no OSHA standard exists, but for which the Company believes medical monitoring is prudent, are offered such medical programs.

Standard Oil has demonstrated its dedication to a healthy workplace by implementation of policies ensuring the protection of employee health and promoting employee safety. The Company provides many employees, based upon their age, periodic health evaluations unrelated to potential workplace exposures, as preventative medical programs. Employee health education information and fitness programs are also offered. Finally, the Company has taken a strong position for a healthy workplace with initiatives against smoking and substance abuse by employees.

We strongly believe that where studies indicate an adverse health effect from materials or physical agents, individuals exposed to harmful concentrations must be informed. In fact, Standard Oil, in the past, has taken steps to notify workers and consumers about the potential health effects of our products and worker protections, despite the often detrimental effects of such announcements in the marketplace.

In view of our commitment and dedication to worker health and safety, Standard Oil supports the prevention of occupationally-related illness in employees.

However, we believe the mechanisms proposed in S. 79, as currently drafted, are seriously flawed and will not achieve the stated goal of disease prevention. Furthermore, if enacted in its current form, S. 79 would burden U. S. industry and the public with the costs of a new notification bureaucracy leading to individual anxiety and unfounded litigation.

S. 79 uses an unsound approach to the determination of populations at risk; does not provide for sufficient expertise for sound decision making; lacks adequate peer review and public comment period; establishes a notification quota which is inappropriate and which would undermine the credibility of the notification program; creates a new, expansive and costly bureaucracy which would duplicate many existing programs within other agencies; has the potential to mandate inflexible standards as opposed to more effective guidelines relative to medical surveillance and monitoring; lacks necessary provisions for judicial review; and lacks adequate protection against unwarranted litigation and compensation claims.

Passage of S. 79 and implementation of its current provisions will result in significant regulatory and program duplication, massive economic burdens on the public and industry in this country, jurisdictional conflicts between federal agencies, intolerable escalation in frivolous tort actions against businesses, and a basic threat to the viability of many smaller U. S. businesses.

The focus of any federal legislation in this area should be directed to strengthening the many programs already currently in place under federal agencies, and ensuring that workers (both current and former) and the public are informed promptly of substances identified by scientifically accurate epidemiology studies which cause adverse human health effects.

Standard Oil encourages Members of Congress to oppose S. 79 and to carefully consider the principles outlined in our following comments and the alternative proposal, S. 638, introduced by Senator Quayle. Congress should review the extent of current regulations and policies in the area of worker disease notification and prevention and proceed with deliberate care in the development of any further federal legislation concerning worker disease notification.

Specific Concerns With S. 79

Our specific problems and concerns with S. 79 are as delineated below:

1. S. 79 uses an unsound approach to the determination of the "population at risk" which would result in notification of workers who are not really at increased risk of occupational disease. Notification could be triggered by only one "statistically significant" animal or laboratory study indicating that acute or chronic health effects may occur in exposed employees. This notification trigger provides inadequate assurance that several critical epidemiological principles are properly addressed (e.g. strength of association, dose response relationships, biological plausibility, attributable risk, temporal relationships, significance of conflicting or negative studies, the role of contributing causal factors, the extent and seriousness of risk, and consistency of evidence).

2. The notification quota contained in S. 79 (100,000 to 300,000 employees per year) is inappropriate and a complete and unjustified departure from scientific principles. The actual number of workers requiring notification could be higher or lower and should not be established arbitrarily prior to the scientifically-valid determination of the "population at risk". Furthermore, notification quotas and targets undermine the credibility of a scientifically-based notification process and run the risk of generally being ignored by the recipients of the notification. Workers or former workers, who in fact are not at risk but were improperly notified in order to meet a notification quota, could:

   - be subject to unnecessary and unduly expensive medical surveillance;
   - sustain unnecessary emotional stress from misclassification of risk; or
   - initiate unfounded tort liability and compensation claims.

3. S. 79 does not provide sufficient expertise for sound decision-making. For example, the Risk Assessment Board consists solely of Public Health Service employees with no expertise from industry, labor, or academia. The Board would, therefore, have no representation from professionals outside of the government. In addition, the

provisions for expert peer review of the findings and decisions of the Risk Assessment Board are lacking and an insufficient public review and comment period is provided.

4. The attempt of S. 79 to insure scientific validity to epidemiological studies used as the basis for notification is inadequate because ill-defined standards are established in lieu of general guidelines. Standards infer inflexible rules which, when applied to every study routinely, may fail to be applicable to specific studies. In contrast, guidelines infer general principles underwhich one can consider the scientific merit of diverse study protocols. There are already acceptable guidelines developed by scientifically respected work groups and federal agencies which could be used in S. 79: e.g. (1) Report of the Subcommittee Counselors, February 15, 1986; (2) Guidelines for Documentation of Epidemiological studies, American Journal of Epidemiology, 114, 609-613, 1981; (3) Guidelines for Carcinogen Risk Assessment, Federal Register, 51, (185), 33991-34053, 1986; (4) Chemical Carcinogens. A Review of the Science and Its Principles, Federal Register, 50(50), 10372-10442, 1985.

5. Some of the requirements of S. 79 for informing employees of health hazards would duplicate existing programs under EPA's Office of Toxic Substances, OSHA's Hazard Communication Standard, numerous individual State Right-To-Know laws and the Mine Safety and Health Act. In addition, similar functions exist in the Disease Registry (ATDSR), located within the Center for Disease Control, under EPA provisions mandated under CERCLA (1980) and SARA (1986). It is important to remove such overlap to avoid the time and costs associated with duplication of efforts.

6. The certification of employers to conduct notification of "populations at risk" of former or existing employees is unclear in S. 79 with respect to whether or not the employer may elect to accept or decline this responsibility. This area of the bill needs to be clarified to allow employers who wish to notify existing or former employees the flexibility to do so, and the right to access necessary governmental records.

7. S. 79 directs the Risk Assessment Board to first designate employee "populations at risk" likely to benefit from medical surveillance or health counseling. As noted

above, guidelines rather than standards should be established by the Board, and latitude should be provided to the employer's licensed medical professionals to decide what medical procedures or tests would be deemed useful in the medical surveillance program. Developing technology not yet in universal use or highly specialized tests, should not be mandated. Furthermore, costly screening programs that fail to detect diseases sufficiently early to alter outcome, or tests that detect disease for which no medical intervention is feasible, do nothing to prevent illness. S. 79 also fails to ensure employee cooperation with employer efforts towards appropriate medical monitoring, nor does the bill assure employer access to relevant employee medical information to assist with preventive medical measures.

8. The standard for judicial review in Section 5 is based on "arbitrary and capricious" rather than the "substantial evidence" test. This basis for judicial review, in lieu of evidentiary fact, is inappropriate considering that the Risk Assessment Board's findings and impacts are based on evidentiary and material fact.

9. As a consequence of the arbitrary and unscientific basis for identifying "populations at risk", the bill would lead to substantially increased and unwarranted litigation and compensation claims.

In view of the above concerns, The Standard Oil Company opposes enactment of S. 79 as currently drafted. Because of the high costs, both direct and indirect, associated with federal legislation in the disease notification area, we urge Congress to use careful deliberation on this issue. Federal legislation, if any, must be designed which only notifies those persons truly at risk of an occupational disease who will benefit from such notification. In addition, sufficient safeguards must be enacted to prevent the notification from being misused in any subsequent legal proceedings. As currently structured, S. 79 does not achieve any of these critical requirements.

Suggested Approach To Worker Protection And Notification

Any health risk notification program should be founded on established, approved and scientifically sound principles. To this end, inclusion of the following epidemiological concepts are essential: the statistical reliability of the human study test results; the significance of the human health risk; the duration and intensity of exposure in the study; the consistency of all evidence indicating positive findings; the medical benefits that might result from notification; the potential effects and benefits of failing to provide notice; the potential effects of providing incorrect notice; and specific circumstances under which the results of the study justify notification outside of the population studied.

The key components of any federal notification program should be based on the following important factors:

Significant scientific evidence, including epidemiological studies and other relevant information rather than merely the results of only one study.

- Notification decisions should be at the discretion of acknowledged and experienced scientists and should incorporate adequate peer review, public comment, and other rulemaking procedures.

- Safeguards to avoid and prevent indiscriminate and erroneous notification.

- Adequate protective measures to avoid an onslaught of unwarranted tort actions and workers compensation claims.

Standard Oil's Experience With Employee Identification And Notification

Employer cohort determination and notification represents a tremendous undertaking, both in resources and in time. The Standard Oil Company's experience with identifying 2,000 employees, 1,500 of which were former employees for a plant started in the 1960s, has shown that many manmonths of effort are required to simply identify the appropriate persons within the cohort. These activities required the assistance of the Social Security Administration (SSA) for the purposes of acquiring worker identity information. It often takes SSA in excess of six months to respond to these requests. Once this information has been obtained, exhaustive review is required to extract only the appropriate employees from extensive and often duplicative listing of names.

Use of the SSA for personal identifiers is a common tool used in epidemiology. If many companies were required to initiate similar requests to SSA because of mandated notification, the increased burdens on SSA could very well lead to extensive and unpredictable delays in securing needed information to support employee identification and notification.

Once the cohort is identified, locating the employees (in particular, former employees) presents another extremely difficult, time consuming and expensive task. Certainly, a number of former employees may remain active on company books through continuation of medical and benefits programs. However, many will be lost to tracing because of geographical relocations. Locating individuals who have completely severed relations with an employer, presents a formidable and sometimes impossible challenge.

A prudent approach to ensure an effective and timely notification process would involve federal notification with an option for individual employers to undertake notification activities on a voluntary basis.

Additional major problems in identifying and contacting all persons ever employed in a specific facility and exposed to a specific agent, from our experience, are discussed below:

1. Identifying specific employees: The major sources used to identify employees, current or former, are the personnel record systems and benefits programs within each company. Personnel record systems may not be centralized and may not be computerized. Benefits programs identify only those employees receiving current benefits. Business operations historically have been sold with all records or conversely acquired with incomplete or non-existent records. Employees who leave the company before being eligible for company health and retirement benefits are usually extremely difficult to locate.

2. Identifying exposures to specific agents: Agents recognized as being potentially hazardous today, formerly may have been considered innocuous and, therefore, records of potential exposure to such agents often are incomplete or non-existent. These agents may have comprised only a small or transient part of the production process, with only a few employees in a plant actually potentially exposed. The employee records at the facility, however, may not identify those specific exposed employees.

3. Locating employees for notification: Notification of previous employees requires two steps: (1) verfication of vital status, and (2) determination of current address. The former must be provided by the SSA, while the latter may be available only from federal agencies (e.g., SSA, the Internal Revenue Service) or state agencies

(e.g. the Motor Vehicle Registration). These data bases for current addresses are generally not accessible by employees.

A prudent and expedient approach to worker notification would involve federal notification using the various data bases available to it with an option for individual notification by an employer on a voluntary basis.

Senator Quayle's Alternative Bill (S. 638)

Senator Quayle has introduced alternative legislation, S. 638, which offers significant improvements over S. 79. In particular:

- The Secretary of Human Health and Services and the Director of The National Institute of Safety and Health are directly involved in the development of procedures governing the efficacy of determination and notification of populations designated to be at risk of contracting occupational disease.
- While notification of former employees is primarily defined as the responsibility of the federal government, cooperation is fostered between the government and private employers which will permit those companies, who so desire, to notify their former employees.
- More extensive peer review procedures are incorporated which permit access to study results indicating any potential risk of disease.
- Protection against the use of the notification in any subsequent legal proceedings is addressed in a definitive manner.

Standard Oil is still assessing S. 638 and would appreciate the opportunity to provide substantive comments on that legislation at an appropriate later time.

Summary

In view of the above concerns, The Standard Oil company opposes enactment of S. 79 as currently drafted. Because of the high costs, both direct and indirect, associated with federal legislation in the disease notification area, we urge Congress to use careful deliberation on this issue. Federal legislation, if any, must be designed which only notifies those persons truly at risk of an occupational disease who will benefit from such notification. In addition, sufficient safeguards must be enacted to prevent the notification from being misused in any subsequent legal proceedings. As currently structured, S. 79 does not achieve any of these critical requirements.

The Standard Oil Company encourges Members of Congress to oppose S. 79 and to carefully consider our comments and the principles outlined in the alternative bill introduced by Senator Quayle (S. 638). We urge deliberate care in the development of any federal legislation concerning worker disease notification.

The Standard Oil Company appreciated the opportunity to provide our views on this most important issue.

S.79

THE HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987

Statement of the

AMERICAN SUBCONTRACTORS ASSOCIATION

to the

SUBCOMMITTEE ON LABOR
COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

March 6, 1987

AMERICAN SUBCONTRACTORS ASSOCIATION 1004 DUKE STREET, ALEXANDRIA, VA 22314-3512
(703) 684-3450

THE HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987

The American Subcontractors Association is a national trade association with more than 6,500 members representing all major construction trades in 55 chapters. In addition to its individual company members, ASA represents 15 other specialty trade associations with members of their own.

ASA is the only national organization that speaks exclusively for the interests of construction subcontractors, regardless of their trade specialty or labor practices. ASA is dedicated to improving general business conditions for subcontractors through unified and cooperative actions.

AMERICAN SUBCONTRACTORS ASSOCIATION 1004 DUKE STREET, ALEXANDRIA, VA 22314-3512
(703) 684-3450

The American Subcontractors Association, as well as other representatives of the construction industry, supports continuing efforts to make construction sites as safe as possible for those who work in the industry. ASA strongly believes that workers have a justifiable "right to know" whenever they may be placed at risk due to occupational hazards on the job and regrets any occurrences where this may not have been the case. In addition, workers should be notified as early as possible about what diseases they may have been exposed to and what steps they should take to combat it.

However, ASA is concerned about attempts by Congress to legislate a program to notify workers at risk that is not only costly, but essentially duplicates existing occupational hazard standards already in existence at several government agencies. A program such as the one proposed by this Committee is essentially unnecessary to achieve its stated goals.

The Issue:

The High Risk Occupational Disease Notification and Prevention Act of 1987 attempts to protect workers through a systematic process of identification, notification, medical testing, evaluation, monitoring, and enforcement.

The bill would initially create a "Risk Assessment Board" within the Department of Health and Human Services (HHS) to determine which past and present employees have been or are currently at risk in a particular job or occupation and which ones need to be identified. This process is made even more complicated because the Board must determine which cases receive priority medical attention and counseling. Public comments are required for the determinations of the populations at risk, with final determinations subject to judicial review which is both arbitrary and capricious.

Once designated populations are identified as being at risk, HHS or an HHS-certified employer, state, or local government must notify each individual employee--current or past-- that has been designated as being at risk. S.79 has a notification goal of 300,000 persons per year and a minimum notification goal of 100,000 persons per year. It requires notifying persons who have been at risk over the past 30 years.

Employers of persons who have been notified as being currently at risk must provide medical testing, evaluation and monitoring services to the employee at the employer's expense except in cases where the exposure did not occur on the present job. This standard applies to both current and past employees.

In order to comply with S.79, the Secretary of Health and Human Services must establish within 90 days of enactment at least 10 but no more than 50 Occupational and Environmental Health Centers. There must be no more than one center in each state. The centers will provide education, training and technical assistance to the professionals who administer to those identified as being at risk.

In addition, the Risk Assessment Board must conduct or provide for research, training and education aimed at improving the means of identifying employees exposed to occupational health hazards and providing medical assistance to such employees. HHS may authorize injunctions through federal district court against violators of the Act, and damages may be awarded regardless of whether the employer's violation was made "willfully."

Analysis and Impact of the Legislation:

As was stated earlier, ASA strongly endorses the intent of this legislation, but the mechanics of it are essentially flawed. One of the main problems with the bill is that it is redundant and repetitive. Most of what the legislation sets out to do can be accomplished by a variety of existing programs and standards. Already in existence is the Occupational Safety and Health

Administration, the Environmental Protection Agency, the National Institute for Occupational Safety and Health, the Consumer Product Safety Commission, the Food and Drug Administration, the Center for Disease Control, the Toxic Substances Control Act, the Federal Insecticide, Fungicide and Rodenticide Act, the Superfund Amendments and Reauthorization Act, and the Resource Conservation Recovery Act. All of these agencies or acts deal with the adverse health effects of toxic substances in some detail, and this legislation will only make an overburdened bureaucracy more bloated and less effective.

More specifically, OSHA's Hazard Communication Standard, which is already the most expensive in history, is being tailored to the construction industry for implementation soon. This is being done for our industry as well as others. With this mechanism already in place, this legislation would only make the current system more complicated and more obtrusive. The increasing costs to employers will rise even more with enactment of such legislation.

Perhaps the greatest fear of this legislation is its potential for a liability explosion. It goes without question that the number of lawsuits due to this legislation will skyrocket. The sheer fear of exposure to some disease will send droves of disaffected present and former employees into the courts. ASA is not against the awarding of damages based on gross negligence, but this legislation, with its goal of notifying 300,000 workers per year, will send many of those who have been notified into the courtroom based on their fear of developing some disease, even though that might never happen. Indeed, the legal precedent has already been set which holds that the fear of exposure is a compensable injury.

The National Association of Manufacturers cites an example in this respect which could hold true for just about any industry: In 1980, approximately 800 employees of one company in August Georgia were notified that they were at an increased risk of disease. As a result, $335 million in lawsuits were filed against an already bankrupt company. If the 100,000 goal of the legislation is met, and only 10% of those notified enter into litigation and recover an average of $100,000 in damages; it will cost businesses and ultimately the consumer over one billion dollars a year.

NAM cited this example in manufacturing. The impact on the family-owned small subcontracting firm could be even more devastating. It would undoubtedly take only one well-financed lawsuit to send a small business into bankruptcy court, and the chances for recovery would indeed be minimal. Also, the additional insurance, monitoring and workhours needed will needlessly add additional strain on small businesses. This intrusion by the federal government is just one more hurdle that small businesses face, and ASA believes that existing health standards are already adequate in this respect.

The feasibility of implementing this legislation in the construction industry is highly doubtful. Subcontractors have a seasonal, transient workforce and work on a contractual basis. Are all transient workers going to have to be tracked down to be notified? There are so many circumstances in the industry that are out of the reach of the subcontractor. Who is to take responsibility for a painting contractor who mixes two substances he purchased at a hardware store and produces a toxic fume? The normal business practice is for the salesman to notify the customer of any safety risks involved. In such a situation, should the salesman be liable? It is highly unlikely that anyone would say that he is.

The financial burden on the small subcontractor would be enormous if this standard were to be enacted. For example, it is estimated that there are 25,000 painting firms in the U.S. and that over 200,000 employees work in small, small-to-medium, and medium shops. Excluding the employees who work in the large firms:

To comply, 22,000 companies would have to:

1. Establish a written hazard communication program. Allow each firm an average of 10 hours at $25.00 per hour (22,000 x 25.00 x 10) = $1,100,000.00.

2. Establish a Material Safety Data Sheet (MSDS) file, storage, retrieval, and updating system. Allow each firm an average of 4 hours at $25.00 per hour; plus a file type of system; plus one hour of training of someone to file, update and retrieve. (88,000 x 25.00) + (22,000 x 50.00) + (22,000 x 25.00) = $3,850,000.00

3. Initially train all employees. Allow for 200,000 employees @ 2 hours each (average wage of $12.00 per hour) = $4,800,000.00. Administrative time to be allowed for the initial training-- 22,000 firms at 4 hours each (2 hours prepratory and 2 hours with the employees) @ $25.00 per hour = $2,200,000.00.

4. Follow-up updated training for new employees, new products and new processes. Estimate that each of the 22,000 firms will have to have at least 12 sessions (one per month) to update or initially train one or more newly hired employees. Allow for 22,000 x 12 x (2 hours administrative and 1 hour employee) = $16,368,000.00.

The total possible projected cost of total implementation across the board in the painting contracting industry is $28,318,000.00. Allowing that some of the training costs would be overlapped and should not be counted twice, it is reasonable to expect a projected cost to this one segment of the construction industry to be $20,000,000.00. The figure would undoubltedly be extremely higher for the industry as a whole.

On any given construction site--both new and remodel sites--when a painter is doing his work, there are a multitude of other craftsmen who are exposed to the hazardous materials being used. This not only applies to painters but also to roofers, concrete forms, plumbers, carpet layers, electricians, welders, air conditioner contractors, etc. Who is to assume the repsonsibility for the plumber being exposed by the painter? This legislation is much too vague to make a determination in this respect.

Using only painters as an example, to extend a hazard communication standard to all segments of the construction industry, it would become the responsibility of the painting contractor to have available at the work site:

1. The written Hazard Communication Program for other affected or exposed craftsmen.
2. The MSDS would have to be available (either at the site or in some easily accessible location).
3. A training program to protect those exposed to the hazardous materials would have to be implemented.
4. The same updating requirements that hold for a single manufacturing facility would have to be implemented at each common craft site.

Allowing for 25,000 painting firms that work on approximately 50 different sites per year, there would be an addtional cost of $12,500,000.00 if each site could be done for just $10.00 each.

If the extra costs sustained by the other craftsmen and the general contractor for coordinating this information are added in, the total could easily reach into the hundreds of millions.

Where do proponents of this legislation think the eventual costs are going to be absorbed? They will either be paid by small firms which may have gone bankrupt because of the burden or they will be passed onto the consumer.

Summary:

ASA questions the scientific and legal bases on which this legislation is based. The methods of determining those at risk are contrary to established scientific practice, and the legislation sets a statistically unreliable figure for demonstrating a population at risk (a 30% increase in harmful effects based on evidence available, which may only be one, unsubstatiated study).

The bill includes broad and ill-defined language, and it essentially makes no connection about concomitant causes of disease, such as non-occupational exposure and personal habits. Indeed, even proponents of this legislation have publicly stated that cigarette smoking could substantially increase a worker's chances of developing a disease. It is also rather frightening to think that notification could come about through one "statitiscally significant" laboratory animal study of chronic health effects.

The makeup of the Risk Assessment Board, a politically- appointed body totally comprised of Public Health Service officals, can make broad determinations without input from the industries involved. Each industry is better equipped to deal with its own employees rather than grouping them together under one program. This Board will undoubtedly be open to many outside influences. In addition, the goal of 300,000 workers notified is a totally arbitrary figure. What if the medical necessity is not present in any given year? 100,000 persons will still have to notified as mandated by this bill.

ASA urges Congress to defeat this legislation because it is unnecessary and overly burdensome for the small businessman and the construction subcontractor in particular. No matter how well-intentioned this legislation might be, its enactment could be devastating.

AMERICAN COUNCIL ON EDUCATION
Division of Governmental Relations

March 16, 1987

The Honorable Howard Metzenbaum
Chairman
Subcommittee on Labor
Committee on Labor and Human Resources
United States Senate
Washington, DC 20510

Re: S 79

Dear Mr. Chairman:

On behalf of the American Council on Education, an association representing over 1,400 colleges and universities, and the associations listed below, we would like to submit our comments on S 79, the High Risk Occupational Disease Notification and Prevention Act of 1987 and request that this letter be made part of the hearing record.

The higher education community supports the concept of notifying past and present workers of their exposure to potentially hazardous substances in the workplace. This is a legal, moral, and educational obligation that we undertake on behalf of our faculty, students, and staff. Colleges and universities are committed to teaching and utilizing the highest standards of laboratory safety and support the goals of S 79 with the reservations and suggested modifications noted below.

We would like to commend you for your decision to develop an alternative to the original provisions of Section 8(c) of the bill. We are pleased with the cooperative efforts extended by you and your staff to representatives of the academic medical community . We are all pleased that you have chosen positive proposals rather than coercive prescriptions to deal with the growing problem of occupationally related diseases.

Our employees need to know if they are at risk of contracting an occupational disease, how great the actual risk is, and to be informed of the signs and symptoms of the onset of a disease. We are concerned however that the legislation as currently drafted could adversely affect the ability of some colleges and universities to obtain insurance for workers who may be defined as "at risk" of disease from occupational exposure to hazardous substances. The bill could also have the unintended impact of either dramatically increasing the cost of insurance or eliminating the possibility of obtaining health, life, and worker compensation insurance presently covering employees. We hope that the insurance issue will be fully addressed during the hearings and that colleges and universities and small businesses will be assured that adequate and reasonable insurance coverage will be available.

One Dupont Circle Washington, D.C. 20036-1193 (202) 939-9355

Additionally, S 79 could cause substantial over-notification to workers not actually facing a significant risk. This process could cause unwarranted anxiety on the part of notified employees and undesirable burdens, including potentially unfounded tort and workers compensation claims, on employers without any offsetting benefits to public health. Indeed, legal precedent exists to support the proposition that the fear of contracting an illness is a compensable injury. Providing additional procedural safeguards in the notification process would prevent both employers and employees from incurring unnecessary additional costs.

We strongly support the proposition that workers should have meaningful access to and be trained to understand information concerning the hazards of the substances with which they work. Medical surveillance programs, early detection, and the implementation of intervention strategies will substantially diminish the human and dollar costs of exposure to occupational disease. Resolving some of the issues noted above could promote a more effective, efficient environment for workplace health and safety while precluding avoidable escalation of employer cost.

The following associations join ACE in this statement:

American Association of Community and Junior Colleges
American Association of State Colleges and Universities
Association of American Universities
Association of American Medical Colleges
Association of Catholic Colleges and Universities
Association of Jesuit Colleges and Universities
Association of Urban Universities
Council of Independent Colleges
National Association for Equal Opportunity in Higher Education
National Association of College and University Business Officers
National Association of Independent Colleges and Universities
National Association of State Universities and Land-Grant Colleges
National Association of Schools and Colleges of the United Methodist Church
National Association of Student Financial Aid Administrators

Sincerely,

Sheldon Elliot Steinbach

Sheldon Elliot Steinbach
General Counsel

cc: Members of the Subcommittee

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March 18, 1987

The Honorable Howard Metzenbaum
Senate Russell Office Building, Room 140
Washington, D.C. 20510

Dear Senator Metzenbaum:

The American Industrial Hygiene Association is pleased to be able to comment on the proposed S.79 bill, the "High Risk Occupational Disease Notification and Prevention Act of 1987"

The American Industrial Hygiene Association was founded in 1939 and is the world's largest professional association which seeks to prevent, through public health industrial hygiene practice, occupational diseases and injuries. The Association has approximately 7,000 regular members and about 2,500 affiliated members in its more than 60 local sections in the United States and worldwide representing labor, academia, government, and the private sector. We publish the major peer-reviewed journal in industrial hygiene and sponsor a major annual conference as forums for interchange of scientific views and elicitation of new information and understanding of means of preventing workplace illness.

The American Industrial Hygiene Association is dedicated to the premise of reducing occupational disease through concepts of anticipation and recognition of excessive employee exposures, evaluation of the level of exposure and estimation of risk, and controlling exposures to the lowest level practical in any given setting. We support the concept of employee education and notification. In fact, such activities are currently important parts of the professional responsibilities of many industrial hygienists. However, at no time do we warn a worker that he or she is at risk when in fact he or she is safe, and, conversely, we do not assure employees of their safety when they are in danger of being excessively exposed. Strengthening the legal requirement for employee notification will help us and others obtain the resources we need to improve the health and safety protection services for Americans at work.

As a consequence of our mutual interests, the Association supports the goals and several provisions of this bill. However, there are a number of provisions within the bill which deeply concern us as professionals. Our collective experience and perspective enable us to suggest improvements which we believe will significantly increase the overall effectiveness of the legislation. The differences of opinion with regard to these issues stem from their complexity. The issue of hazard identification is simple only in the abstract; in reality all hazards are relative. It is important that more realistic and practical consideration be written into several key provisions of the bill to minimize future disagreements. It is in this spirit that we offer these suggestions and comments.

The attached analysis of the bill explains a number of the above concerns in more detail, suggests improvements in specific areas (underlined), and discusses areas which need more careful consideration.

We believe that the goal of notifying employees of current hazards is achievable within the context of the existing Hazard Communication Standard. However, this standard does not provide either for notification of retrospective exposures or for medical surveillance as envisioned within S.79. While we hope to work with Congress to implement our suggestions and enact better, sound, workable health and safety programs, in the long run we would like to see future legislative emphasis placed upon the prospective aspects of anticipation, control, and prevention via current work practices, rather than upon retrospective programs of identification and notification of uncontrolled past practices.

We would be glad to offer our future thoughts, advice, and help in improving the occupational health services available to our citizens. For immediate assistance, please contact Dr. William Popendorf at 319-335-4213. Dr. Popendorf, Associate Professor at the University of Iowa, is Secretary of AIHA and is chairing our task force on developing comments on S.79. Dr. Popendorf's mailing address is University of Iowa - Oakdale Campus, Institute of Agricultural Medicine AMRF, Iowa City, IA 52242.

Thank you for your consideration.

Respectfully yours,

Alice C. Farrar

Alice C. Farrar, CIH
President

Comments on Senate Bill S.79

the "High Risk Occupational Disease Notification and Prevention Act of 1987"

by the

American Industrial Hygiene Association.

18 March 1987

Our comments and suggested improvements fall principally into six areas:

1) The structure of the Risk Assessment Board is designed to maximize independence and minimize outside input. Because of this independence (whether it is good or bad), we feel that some practical, scientific, and humanistic assurances need to be written into the legislation before the process intended by it becomes bogged-down in judicial squabbling over their "independent" decisions.

2) The concept of dose-response needs to be written into the hazard determination and notification processes. This can be accomplished by requiring that exposure be incorporated into the designation of populations at risk. Such a designation could be implemented by the Board, for instance, by designating a low-risk threshold within the descriptive class or category of high risk employees.

3) The concept of relative risk should also be written into both the hazard determination and notification processes. The key terms here are the frequency and severity of the disease. This will assure some reasonable setting of priorities as to who gets notified and what that notification contains. It cannot be assumed that all risks and notifications are created equal.

4) Numerical goals should be eliminated from the proposed legislation. This would pertain to either relative rates of disease or to numbers of notifications made per year. Both goals are likely to lead to the implementation of poor scientific or public health policies.

5) The review, identification, and designation functions of the Board should be separated from the conduct of the supporting research and education functions. Conducting both functions would only encourage disagreements and agencies such as NIOSH and others already exist within HHS which carry-out the latter functions to the best of their funded ability.

6) Changes are needed in the comprehensive and relatively automatic notification procedure required for all new epidemiologic research. The proposed requirement would not provide for adequate review by the Board, would in fact preempt much of their function in a short time, and is not practical or even possible for some otherwise valid epidemiologic study designs.

Other more general clarifications of intent are needed in a few provisions, for instance, those regarding the role of the current employer of previously exposed employees, the potentially inequitable impact of the medical transfer protections upon previously employed "populations at risk", and the relationships of disease determination, notification, and detection upon the workers' compensation and tort liability systems. The following comments are presented relative to their corresponding sections of the bill with specific suggestions underlined.

Section 1. Short Title

While the title "High Risk Occupational Disease Notification and Prevention Act" is comprehensive, as industrial hygienists we feel there is a distinct lack of prevention within this act. For instance, prevention is not even mentioned within Sec. 2(b) "Purpose". The thrust of the programs proposed are identification, notification, and medical surveillance. These are worthwhile undertakings, but they are largely retrospective - after the exposure and potential damage has been done. The allocation of resources to detection after the fact is not cost effective. There are few if any known diseases which affect a majority of workers in any setting; those affected by any one disease are in each case a minority, granted one which should be redressed. In comparison, we believe that the cost-benefit ratio of prevention by better toxicologic knowledge, by exposure control, and by education will greatly exceed that for detection, notification, and surveillance. To rectify this imbalance, more or at least equal emphasis needs to be placed by Congress on anticipation of adverse effects and avoidance or reduction of exposures.

Section 2. Findings and Purpose

The need "for increased [epidemiologic] research to identify and monitor worker populations at risk of occupational diseases" is recognized in Sec. 2(a)(10). We agree that more research is needed, and at the same time feel that the limitations of "established epidemiologic, clinical, and laboratory studies" alluded to in the corresponding Sec. 2(a)(7) should also be recognized as making it difficult to meet the specific numerical goals of notification proposed within Sec. 4(b)(3)(C). We will later suggest that those goals be eliminated.

Section 3. Definitions

Careful consideration needs to be made regarding the acceptable criteria for determining an "occupational health hazard." Although this term is defined in Sec. 3(7) as "statistically significant evidence (based on at least one study conducted in accordance with established scientific principles)", there is no generalized agreement concerning what constitutes acceptable "scientific principles." In other words, not all epidemiologic studies are created equal. Almost every study can be criticized by some or many other experts as inadequate or flawed; typically, such disagreements are resolved by conducting yet another study.

One of the first tasks of the Board should/will be to establish a consensus of those "scientific principles", defining acceptable criteria for identifying populations at risk upon which we can all agree. This task will take a finite period of time and seriously affect the ability to meet specific numerical "notification" goals for the first year (as proposed under Sec. 4(b)(3)(C) if adopted), and the criteria themselves will directly affect the number of studies which are judged adequate to justify notification in subsequent years. For the Board to preclude or shortchange adequate forethought and agreement regarding acceptable criteria in the face of forced numerical goals would only encourage poor science, poor public health decisions, and continuing controversy over future decisions of the Risk Assessment Board. This concern is reflected in proposed changes to Sec. 4(b)(3)(C).

One central toxicologic principle of dose-response is recognized in the definition of "Population at Risk of Disease", within Sec. 2(a)(9) viz. "an employee population exposed to an occupational health hazard at intensities or for durations comparable to at least one study" (emphasis added). However, this principle is not carried through later in the bill when identifying (Sec. 4(b)(2)), designating (Sec. 4(b)(3)), and notifying (Sec. 4(c)(2)) other working (and previously working) populations. Carrying this principle through to the designation and notification procedures, would minimize unwarranted notifications, encourage and reward employers who measured and controlled exposures, and provide more valuable information to affected employees and their physicians.

Section 4. Risk Assessment Board

Again careful consideration should be given to the make-up of the Risk Assessment Board. The AIHA could not reach a consensus of the value of outside involvement (non-Public Health Service employees members). Clearly, there will be a great deal of political pressure on the Board regarding their policies and decisions. We feel it is important that such access to outside viewpoints be accommodated, but it is probabilistic whether the best decisions can be made with such viewpoints being expressed from outside versus from within the detailed process. We suggest that the structure of the Board be carefully considered during these hearings and that opinions of all sides and the experiences of other broadly similar boards be sought.

The proposed Board is entrusted with many powers. Among the more scientific is the development of acceptable criteria for the identification and designation of populations at risk under Sec. 4(b)(2) and (3), respectively. While this process could be manipulated, perhaps more serious potential abuses of the Board's powers relate to the authority (under Sec. 4(b)(1)) to request epidemiological information from other agencies or private organizations. This authority coupled with a charge under Sec. 8(a) "to conduct or provide for research..." and the implication under Sec. 12(a) and (b) that any findings demonstrating a population at risk of disease in all future epidemiologic research by any Federal agency shall result in notification of subjects, have suggested to some AIHA members that voluntary cooperation with research proponents will be severely curtailed and that the selection of target industries or political regions could be manipulated. Whether these decisions would be more or less unbiased by broadening the membership base of the Risk Assessment Board is an open question.

There is an important difference and unrecognized leap in faith between the "identification of populations at risk of disease" in Sec. 4(b)(2) and the "designation of populations at risk of disease" in Sec. 4(b)(3). The identification of a population at risk as defined under Sec. 3(9) requires as a minimum only one study "for which there is statistically significant evidence" of association between exposure and disease. But such a finding of statistical association in and of itself does not necessarily mean causation or that it could be reproduced in another setting. We can only assume that the Board will develop a consistent and agreed-upon criteria for the determination of "occupational health hazard" as defined in Sec. 3(7).

A first priority for the Board to consider in designating identified populations for notification is specified in Sec. 4(b)(3)(A), i.e. that designated populations are "likely to benefit from medical surveillance or health counseling." Some lesser factors for consideration are also specified in Sec. 4(b)(3)(B), but the Board is not required to consider relative risk. Given the proposed independent, non-representative make-up of the proposed Board, it is strongly suggested that the magnitude of the health risk, both in terms of the frequency and severity of the disease, be added to the considerations in designating a population at risk in Sec. 4(b)(3)(B).

Statistically significant increases in disease or death rates can be found in a broad range of disease types, some of which are normally frequent in unexposed populations, others of which are normally rare. It is obviously less cost effective to deal with the rare diseases than with the more common; and from the personal and psychological perspective, there may be a questionable benefit to informing an individual that he or she is at risk of a 10-fold increase of a particular cause of death when that cause is 200-fold less likely than other more common non-work related causes (disregarding for the moment the concurrent value of medical intervention in each case which is already written into the proposal). Similarly, for the same (assuming low) frequency of diseases, occupational health hazards which are for instance neurotoxins should be considered more serious than irritants or perhaps sensitizers. For purposes of recognizing current hazards and setting standards, we as industrial hygienists try to reduce exposures for both agents equally, but it doesn't make as much sense to notify a worker that at some point in his or her past they were exposed to an agent associated with a 20-fold increase risk of having been irritated or sensitized, in comparison to having an equal risk of neurologic damage. Inclusion of both "the frequency and severity of the disease" as required considerations under Sec. 4(b)(3)(B) will assure a more well rounded evaluation of the need to notify.

The setting of numerical goals within Sec. 4(b)(3)(C) of the bill should be eliminated. As mentioned earlier, there are several critical first steps which the Board must undertake within the bill and others it should and probably will undertake to establish an effective program of identification, designation, and notification. To force a numerical goal upon the Board would encourage poor science and poor public health decisions.

More guidance needs to be provided to the designation of "classes or categories of employees...being considered for inclusion as an employee population to be notified" under Sec. 4(c). In particular, application of the concept of dose-response alluded to within Sec. 2(a)(9), implies that intensities and durations of exposure should be added to the designation of such employee populations at risk. This addition would have several benefits. First, it would encourage more employee exposure monitoring and create another incentive to reduce exposures in the hope that an employer could keep his employees below a low-risk exposure threshold which might under this concept be set to designate a "population at risk of disease" at some point in the future. Second, it would minimize the number of people needing to be notified to those most at risk. And third, it would make such notification more relevant to the target population actually at risk. One of the operational limitations of the current Hazard Communication standard is the lack of dose-response information in Material Safety Data Sheets. For instance, the hazards of a pure chemical and only 5% of that same chemical in a mixture appear equal on paper when in fact this dilution would cause about a 20-fold difference in exposure and associated hazard. This "overload" of essentially irrelevant information by affected employees could make such a notification scheme meaningless but could be minimized by assuring consideration of dose-response during the designation process.

A related reason for including dose-response within the determination (and the later notification) process is exemplified by the requirement under Sec. 4(b)(3)(B) to consider "exposures for which there exists a permanent standard..." Certainly most if not all permanent standards are based in large part on the fact that excessive disease (or lesser adverse response) would result from exposures above the standard. A conscientious employer would recognized the need to control exposures below this level even before the new standard was set. Unless an exposure-based low-risk threshold were incorporated into the designation of population at risk, these employees would be notified as well as those at "high risk". Such notification is likely to concern the employee needlessly, whereas the existence of a low-risk threshold would be an added inducement to employers to evaluate and control exposures to the lowest feasible level, in anticipation of avoiding future notification requirements. Of course, those employees not protected by on-going environmental surveillance would by default have to be notified.

Section 5. Employee Notification and Counseling

The concept of dose-response and the issue of quantifying the frequency and severity disease risk must be added as part of the "Contents of Notification" under Sec. 5(b)(2) for many of the same reasons noted above for designating populations at risk. The nature of occupational hazards and epidemiologic studies is that they are not distributed equally among all occupations, among all jobs within an occupational "class or category", or among all diseases for which either workers or nonworkers are at risk. By assuring that information on the relative importance of the risk is conveyed to the affected population, individuals and their physicians will be better prepared to evaluate the importance of each occupational risk factor in relation to other non-occupational risk factors as well as to compare among multiple risk factors affecting some populations.

The proposed act (circa Sec. 5(b)) does not state precisely who specifies the counseling information, e.g. who defines "the most appropriate type of medical monitoring for the disease associated with the risk". Although it is stated that "the Secretary shall" do the notifying (which could be NIOSH or perhaps some other agency within the Department of Health and Human Services), by virtue of their review and designation process, it seems logical that the Board is probably in the best position to make that recommendation. This point should be clarified.

Section 6. Means of Employee Notification

There seems to be some ambiguity between Sec. 6(b) and Secs. 6(c)-(d). The former states that in carrying out notifications "the Secretary is encouraged to cooperate to the extent practicable with private employers" but that "no private employer or public agency ... may receive payment for the cost of such notification from the United States, or have a right of access to Federal records..." In comparison to this spirit of cooperation, there are several elements of Sec. 6(c) and (d) which are disincentives for cooperation. These include notifying "employees for whom no exposure to the occupational health hazard occurred in the course of current employment" (for which the current employer would have no knowledge without access to Federal or other records), and additional requirements which are implied if notification is conducted by the current employer who is also "subject to the hazard communication standard with respect to the occupational health hazard in question". There seems to be little incentive for employers to cooperate in this process as stated. Some clarification of the operational intent and restrictions seem to be in order in these subsections.

Section 7. Occupational and Environmental Health Centers

No comment.

Section 8. Research, Training, and Education

We have two reasons to be concerned that under this section the Board (rather than another agency) is given authority to "conduct or provide for research" as well as other aspects of training and education. First is the fact that other agencies are already in place to do, at least in part, occupational health research; NIOSH is prominent in this research field, and they also support occupational health education in a variety of ways. The second is as a result of the Board's review process, there would be a built-in conflict of interest to look more favorably upon their own research and less favorably upon research funded or conducted elsewhere, no matter what the objective quality of either agency. We therefore recommend that the Board be limited to only reviewing the results of others' research and perhaps advising on areas of needed research or research methods. On the other hand, we wholeheartedly support the need for further research in occupational toxicology and epidemiology as well as the more preventive aspects of control of industrial exposures.

Section 9. Employee Testing; Discrimination against Employees

There are some potentially serious inequities built into the provision of Sec. 9(a) that "testing, evaluation, and medical monitoring ... shall be provided or made available by the current employer." Perhaps there is an assumption that the majority of employees so affected will still be employed by the same employer as at the time of exposure. On the other hand, it is likely that many if not most employers will not be the otherwise responsible party. This alternate hypothesis is due in part to changing technologies and workforces, to the equally large or larger number of hazards among small, less stable employers, and to the 30-year historic record written into the act. Moreover, a significant number of employees suffering only partially disabling diseases are likely to have migrated from large to small or medium employers for whom such medical services would represent a larger proportionate cost, and for whom the medical transfer protection clause described in Sec. 9(c) of intra-employer transfer to a less hazardous or nonexposed job at equal pay etc (including providing medical transfer protection "where said job is not available, for a period determined by the physician not to exceed 12 months.") may not be a viable alternative either. Some further considerations of these potential inequities for employers and employees is in order.

Section 10. Enforcement Authority

Although Sec. 10(g) clearly states that notification of an employee as part of a population at risk "shall not constitute or in any way affect a claim for compensation," the above inequities and the lack of medical surveillance coverage for unemployed persons highlights the dilemma posed on the one hand by informing people of their risk of disease while on the other hand implying (depending upon state laws) that the development of such disease may not be compensable under worker compensation protection laws. We see no simple way around this dilemma, but reiterate that the issues are complex and should require thoughtful consideration before implementing this act.

Section 11. Reports to Congress

No comment.

Section 12. Subjects of Federal Agency Studies

There are some serious inconsistencies in the requirement under Sec.

12(b) that "all occupational epidemiologic studies conducted by a Federal agency initiated after the effective date of this Act shall include in the study design specific methods for notifying living subjects or their immediate family members that they are part of a population at risk of disease." The first inconsistency is that there is no obvious "preventive" or other prospective benefit (such as medical surveillance) to be gained by notifying "immediate family members" other than for the purposes of workers' compensation or liability claims (which are ostensively exempted under Sec. 9. Second is the implication that such notification is automatic rather than subject to review by the Board; historically many (certainly not all) "positive" studies have later been found incorrect, misleading, or at least not duplicatable; therefore, all future studies should be subject to the same validation criteria before notification is implemented. Third, the names and other identifying information of "participants" is not always available to the researchers; for example, mortality studies based on death certificates would not necessarily include full names and addresses of immediate family members, but are a valuable tool to epidemiologists. We suggest that this Section be eliminated or reworded either to have the Board review and determine the notification action appropriate for all future Federal studies (which they should eventually do under other sections of this act, anyway) or to require that the procedures for notifying the subjects as established by other Federal agencies be consistent with the review and notification requirements of the Board.

Section 13. Regulations

No comment.

Section 14. Authorization of Appropriations

Finally, on a somewhat lighter note, it seems difficult to make $5,000,000,000 available for research out of only $25,000,000 appropriated. An oversight we presume.

Section 15. Effective Date.

No comment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

January 27, 1987

Dear Participant:

I write to bring your attention to an important meeting concerning exposure registries. On March 23 - 24, 1987, at the Westin Peachtree Hotel here in Atlanta, the Agency for Toxic Substances and Disease Registry (ATSDR) will convene a National Workshop on a National Registry of Persons Exposed to Hazardous Substances. This is an announcement for you and/or your representative(s) to attend.

ATSDR has placed high priority on fulfilling its responsibilities under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) that mandates the Agency, in cooperation with the States, to "establish and maintain a National registry of persons exposed to toxic substances". How ATSDR should proceed in meeting this mandate will be the subject of the workshop. We set up a scientific working group with ATSDR and the Centers for Disease Control (CDC) to draft a proposal for a national exposure registry. The methods, procedures, and issues outlined in this document are intended to facilitate discussions at the Workshop.

The first day of the Workshop will consist of a morning plenary session, followed by three concurrent working groups. The second day will consist of a brief plenary session, followed by three more concurrent working groups and a summary session.

The goal of the Workshop is to achieve consensus on the importance of select exposure subregistries, criteria for their establishment, and general principles to be followed in the maintenance and use of the registry. If consensus cannot be achieved, at minimum we hope to identify key points of disagreement that will be referred to ATSDR for final resolution.

A Workshop brochure, ATSDR National Registry Proposal, and a Westin Peachtree Hotel Reservation Card are enclosed for your convenience. If you have any questions, please feel free to contact Dr. Wendy E. Kaye, Chairperson, Exposure Registry Implementation Group, at (404) 454-4592, or me at (404) 454-4590.

I hope to see you at the Workshop.

Sincerely yours,

Barry L. Johnson

Barry L. Johnson, Ph.D.
Associate Administrator

Enclosures

NATIONAL REGISTRY PROPOSAL

Agency for Toxic Substances
and Disease Registry

January 1987

WORKING DRAFT

Working Draft
January 1987

TABLE OF CONTENTS

I. FOREWORD 1

II. BACKGROUND 2

- A. CERCLA 2
- B. Definitions 2
- C. Relationships between Registry, Study, and Health Surveillance 2
- D. Description and Scope 4
- E. Purpose 6
- F. Function 6
- G. Administration 7
- H. ATSDR Relationship with States 7

III. METHODS 8

- A. Introduction 8
- B. Population Selection 8
- C. Population Identification 9
- D. Type of Subregistry 9
- E. Informed Consent 9
- F. Core Data Items 10
- G. Exposure and Enrollment Criteria 10
- H. Data Management 10
- I. Confidentiality 11
- J. Followup 11
- K. Updating 12
- L. Analysis 12
- M. Reporting 12
- N. Termination 13
- O. Science Advisory Board 13

IV. SUBREGISTRIES

- A. Dioxin 14
  - 1. Background 14
  - 2. Population Selection 15
  - 3. Population Identification 15
  - 4. Exposure and Enrollment Criteria 16
  - 5. Type of Subregistry 16
- B. Beta-naphthylamine 17
  - 1. Background 17
  - 2. Population Selection 17
  - 3. Population Identification 17
  - 4. Exposure and Enrollment Criteria 18
  - 5. Type of Subregistry 18

V. ISSUES 19

Working Draft
January 1987

I. FOREWORD

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (known as Superfund) requires the Agency for Toxic Substances and Disease Registry, in cooperation with the States, to establish and maintain a national registry of persons exposed to toxic substances. This document describes the Agency's proposal on how it will meet this statutory mandate and identifies issues to be discussed at a public meeting March 23 - 24, 1987, in Atlanta, Georgia.

The ultimate purposes of a registry of persons exposed to toxic substances are to provide service to registrants and to facilitate the development of new scientific knowledge. Besides identifying and keeping track of exposed persons, a registry should coordinate the clinical and research activities that involve its registrants. Since many researchers may propose using registrants as study participants, the registry should be the focal point of coordination. By maintaining a comprehensive data base on all exposed persons, a registry should try to collect information that satisfies multiple needs. Besides playing an important role in assuring uniformity and quality of the collected data, a registry should ensure that data collection is not duplicative in studies in order to reduce the overall burden to exposed or potentially exposed persons.

The intent of the Agency for Toxic Substances and Disease Registry's (ATSDR) protocol is to provide the framework for the National Exposure Registry. The methods, procedures, and issues outlined in this document are intended to facilitate discussions at the Public Workshop on the National Exposure Registry in March, 1987. The goal of the Workshop is to achieve a consensus on the importance of select exposure subregistries, criteria for their establishment, and general principles to be followed in the maintenance and use of the registry. If consensus cannot be achieved, at minimum, we hope to identify key points of disagreement. These points will be referred to ATSDR for final resolution. Following this Workshop, ATSDR will revise the protocol to encompass the opinions expressed at the Workshop, proceed to resolve any points of disagreement, and commence to establish the National Exposure Registry.

II. BACKGROUND

A. CERCLA

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) created the Agency for Toxic Substances and Disease Registry (ATSDR). CERCLA requires ATSDR, in cooperation with the States, to "establish and maintain a national registry of serious diseases and illnesses and a national registry of persons exposed to toxic substances". This mandate remains under the Superfund Amendments and Reauthorization Act of 1986 (SARA). How to comply with the law has been the subject of considerable review and discussion within ATSDR and the Centers for Disease Control (CDC).

B. Definitions

1. A registry is a system for collecting and maintaining in a permanent record information on specific persons from a defined population.

2. An epidemiologic or health study is the evaluation of specific hypotheses concerning the relationship between an exposure and a health outcome in a defined population.

3. A health surveillance program is the periodic medical screening of a defined population for a specific disease or for biological markers of a disease, for which the population is at significantly increased risk. The program should include a mechanism to refer for treatment those individuals who screen positive for the disease.

C. Relationships between Registry, Study, and Health Surveillance

A registry should identify and track its members effectively and act as a repository for information about them, including information derived from studies or health surveillance of registrants. In performing these functions, a registry can be a very useful tool to facilitate the study, notification, or surveillance of a defined population.

A registry is not a study or set of studies of registrants--a registry should not be confused with short- or long-term prospective cohort studies. A prospective cohort study aims to discover future health status of exposed persons by comparing them to a suitable unexposed group. Since a registry provides a mechanism of identifying exposed persons, it is natural for investigators to use a registry as the basis of selecting exposed participants for study. Because the selection criteria for participation in a study may differ from the enrollment criteria for a registry, a registrant may be asked to participate in several studies, or no study at all. On the other hand, a person who gives a definite history of handling a toxic substance but declines to participate in a study (e.g., one that requires a tissue biopsy) will still be included in registry followup. This is because one of the purposes of a registry is to notify registrants of new findings and recommendations in preventing adverse health outcomes.

Another distinction between registries and prospective cohort studies is that a registry attempts to identify all potentially exposed persons and enroll them continually over time. A prospective cohort study only attempts to assemble a group or "cohort" of exposed and unexposed persons, and to follow this group over a long period. The prospective cohort study does not continue to solicit participation from additional persons after the study has begun, nor does it necessarily try to identify all potentially exposed persons.

Finally, in an epidemiologic study, investigators must demonstrate ahead of time that the study is likely to succeed in achieving its objectives. This demonstration, in part, depends upon the sample size of the study. The sample size must be large enough to eliminate, with reasonable confidence, chance fluctuation as an explanation for the findings. In contrast, a registry is more concerned with potential benefit to registrants and to medical science in the future. Accordingly, the decision to establish a registry is less influenced by sample size considerations.

Just as a registry is not a study, a registry is not a health surveillance program. A registry may be a useful tool for selecting persons at significantly increased risk of disease who need health surveillance, but the definition and the purpose of a registry are fundamentally different than that of a surveillance program. The selection criteria for entry into a health surveillance program will usually be different than the enrollment criteria for a registry. There may even be different surveillance programs for registry subgroups, depending on the extent of their exposure.

A health surveillance program's principal goal is to screen individuals at significantly increased risk of disease and, if they screen positive, to refer them for medical treatment. Screening should only be done if there is a known health outcome which can be prevented or treated more effectively as a result of screening and early detection. In the absence of an effective intervention program, screening serves no medical purpose and may, in fact, be detrimental to the population being screened.

D. Description and Scope

The National Registry will enroll persons who have either been exposed to toxic substances or are believed to have developed disease(s) as a result of their exposure to toxic substances. The Registry will accommodate primarily those individuals whose exposure was associated with a Superfund site, but will also accommodate those whose exposure was from another source, such as a chemical spill or their occupation. The National Registry, however, will not include previously established exposure registries.

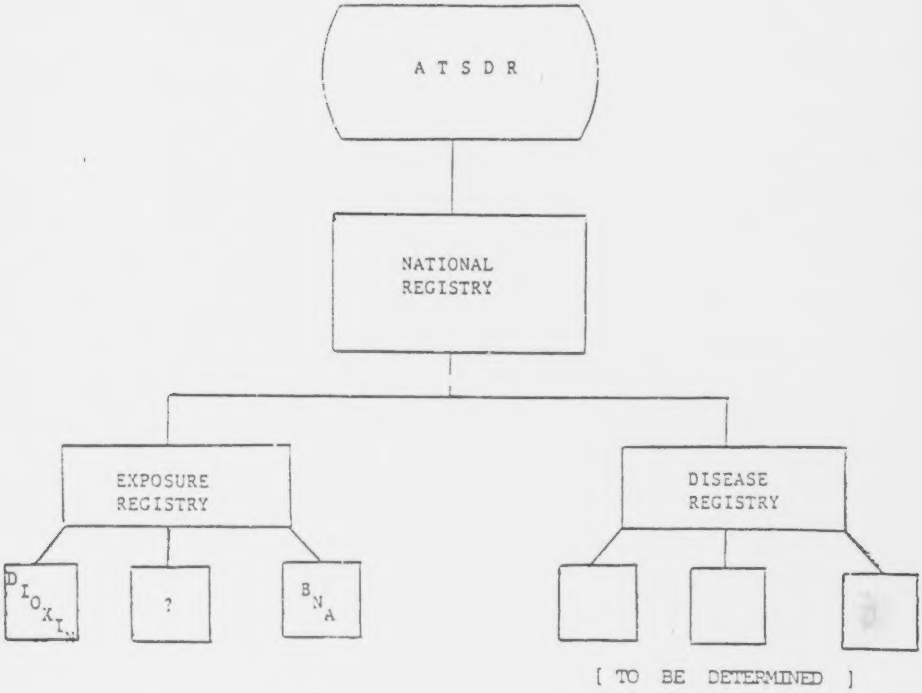
Not included as part of the National Registry at this time are specific diseases believed to be related to toxic substance exposure(s). ATSDR will first begin to establish a National Registry of individuals exposed to toxic substances (National Exposure Registry) and will then begin to prepare a working document examining ATSDR's responsibilities for a National Registry of specific diseases believed to be related to toxic substance exposure(s) (National Disease Registry) including recommendations on how (and if) to proceed.

In addition to personal identifiers, the National Registry will contain information, when known, for each registrant on (1) the type, duration, and degree of toxic substance exposure; (2) the occupational or nonoccupational nature of the exposure; and (3) the geographical location of the exposure.

Although there will be but one National Registry, it will contain subgroups (or subregistries) which will be easily identifiable for the purpose of notification, study, or surveillance of its members (see Figure 1). Each subregistry will be composed of persons exposed to a specific toxic substance or mixture of substances from a specific site under defined conditions. As populations are identified for inclusion in the National Registry, subregistries will be established. Each subregistry will have its own specific scientifically supportable entry criteria (see Section III G).

The first subregistries proposed by ATSDR for inclusion in the National Exposure Registry are: 1) Persons exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin and 2) workers exposed to beta-naphthylamine. For a justification and a detailed explanation of these subregistries see Section IV.

FIGURE 1
ATSDR NATIONAL REGISTRY STRUCTURE


A T S D R
NATIONAL REGISTRY
EXPOSURE REGISTRY
DISEASE REGISTRY
DIOXIN
?
BNA
[TO BE DETERMINED]

The National Registry will be maintained indefinitely, since it is the organizational structure that will contain individual subregistries. A subregistry, however, may have a limited life (e.g., 5, 10, 30 years), and the composition of the National Registry will vary depending upon what subregistries it contains at a given time. Each subregistry within the National Registry will have a definite termination rationale, but the National Registry will continue as long as legislation and funding support its existence.

E. Purpose

The National Registry will serve the following purposes:

1. Enable State or Federal health officials to notify registrants rapidly of adverse health effects of an exposure, preventive measures, or therapeutic advances, which were not understood or known at the time that the subregistry was established;
2. Facilitate State or Federal health surveillance programs by tracking participants in the program and maintaining information on participants;
3. Facilitate epidemiological or health studies, when no other method of followup will suffice; and
4. Provide information that can be used to assess the burden of the effects of an exposure or health outcome on a population.

Depending upon the exposure, the population exposed, and the exposure setting, the National Registry may serve different purposes for different subregistries.

F. Function

The National Registry's principal functions will be (1) to locate and enroll as registrants those persons for whom a subregistry has been established, (2) to track its registrants through time and location, and (3) to store the information on its registrants derived either from the National Exposure Registry's tracking function or from health studies or surveillance conducted on them and, where appropriate, medical referral. These functions are detailed in the Methods Section.

G. ATSDR National Registry Administration

Since many of the activities between subregistries are similar, it would be more efficient for ATSDR to share resources between subregistries. In other words, it would be more efficient for one agency to be conducting registries on multiple toxic exposures. This is because the mechanisms to contact and track people, as well as to manage computer databases, need not be duplicated in separate subregistries for different toxic exposures. For similar reasons, it is also important to have one distinct organizational entity within ATSDR to conduct registry activities with its own director and staff.

ATSDR will establish a Branch for Exposure and Disease Registries within the Office of External Affairs. This Branch will be responsible for, but not limited to the following:

1. Administration and supervision of the National Registry
2. Administration and supervision of contracts
3. Surveillance of data
4. Selection of chemical exposures or sites for future subregistries
5. Development of enrollment criteria for chemical exposures or sites selected for subregistries
6. Liaison with the ATSDR Science Advisory Board

H. ATSDR Relationship with States

The data that comprise subregistries within the National Exposure Registry will result from one or more of the these possibilities:

1. Data collected and funded by States or ATSDR as part of State initiatives.
2. Data collected by States at the request of ATSDR, funded in part or whole by ATSDR.
3. Data obtained from Federal agencies.

Exposure registry information collected by States and Federal agencies would be collected and maintained by ATSDR. States and Federal agencies would have free access to their own data, but access to national data would require ATSDR approval. Such approval would consist of ATSDR's obtaining the advice of its Science Advisory Board in instances of requests for research on national exposure subregistries. In all cases, Federal laws pertaining to privacy, human research, and others that are applicable would be adhered to.

III. METHODS

A. Introduction

This section addresses the general methods that will be used to set up the National Registry. Each subregistry will have its own set of exposure, notification, and termination criteria. Two examples of how specific subregistries will be established will follow this general discussion.

B. Population Selection

There must be an exposed or potentially exposed population before a subregistry will be considered. The determination of whether a candidate population is indeed exposed will involve a two-stage process.

First, a population will be initially considered exposed to a toxic substance if a plausible route of exposure can be postulated. At this stage the identification of a geographical site or source of exposure will provide the framework for identifying candidate exposed populations. Sites will be considered if they contain toxic substances and there is the opportunity for human exposure.

Second, following investigation a population will considered exposed or potentially exposed if there is evidence that supports the postulation that exposure occurred. This evidence may include:

1. documentation of contamination of air, water, food, or location to which the population may be exposed;

2. documentation of health effects or results of biologic monitoring that indicate that exposure may have occurred.

Following identification of potentially exposed populations the priorities for registration will be based on the following scientific criteria:

1. Is the substance(s) in question a known human carcinogen, teratogen, neurotoxin, immunotoxin, etc?

2. Is the substance(s) in question a suspected human carcinogen, teratogen, neurotoxin, immunotoxin, etc?

3. What is the severity of the adverse health outcome: is it permanent or reversible?

4. What is the likelihood that there has been extensive exposure to individuals or to large groups?

5. What is the likelihood that there has been any adverse health outcome? (additional information available from the medical community, health official, and citizens associated with the site)

When considering populations for site-specific subregistries, the following operational criteria will be considered:

6. What is the likelihood that citizens are concerned and will participate in a subregistry?

7. What is the likelihood of being able to provide any meaningful information to the registrants or the local community because of the subregistry?

The ATSDR Science Advisory Board (Section III O) will refine these criteria as one of their first tasks.

C. Population Identification

Once a candidate population has been designated a complete roster of potentially exposed persons for each site will be assembled within each population using tax records, city directories, telephone books, school records, employment records, rental records, etc. It is important that all persons with potential exposures be identified.

D. Type of Subregistry

Two types of subregistries have been proposed, participatory and nonparticipatory.

1. A registry is nonparticipatory when the population at risk is being identified through existing data sources and followed through vital records. The potentially exposed individual is not contacted by the registry.

2. A registry is participatory when the potentially exposed individual is contacted to provide any information that is not readily attainable from existing data sources.

E. Informed Consent

Informed consent will not be required for nonparticipatory subregistries since the individuals will not be contacted. However, when a subregistry requires the participation of its registrants, informed consent will be obtained. Although only verbal informed consent will be necessary for telephone interviews to ascertain exposure information, a signed informed consent will be required from registrants who agree to participate in any health studies or medical surveillance.

F. Core Data Items

Core data items that will be maintained as part of the National Registry will include, when available: name (first, middle, last), address (at time of exposure and most current), telephone number, social security number, date of birth, sex, race, type of toxic substance exposure, nature of exposure (environmental vs. occupational), initial date of exposure, final date of exposure, location of exposure (city and state), and company of exposure (if occupational). For individuals who are deceased, a copy of the death certificate will be requested and key items such as cause of death will become part of the registry. In addition to the core data items, some medical data collected from followup studies and/or medical surveillance will form part of the Registry record. These data items will be determined for each subregistry and will be limited. For some subregistries a means of linking data in the subregistry with all the data from the followup study and/or medical surveillance will be provided.

This information will be key-punched, verified, and checked for consistency. Where possible discrepancies will be rectified and an audit trail will be created.

G. Exposure and Enrollment Criteria

The National Registry should define clearly and specifically the individuals within the population at risk of exposure that it seeks to enroll. Since the National Registry will be open to all United States residents that fulfill subregistry entry criteria, these criteria must be explicit and scientifically supportable. For most toxic substances, enrollment criteria must currently rely on exposure modeling. Because the conditions at different sites vary in terms of person, place, time, and the nature and level of exposure, enrollment criteria for the National Registry must be subregistry and site specific. Although not feasible at present for many toxic substances, entry criteria may come to include the results of biological monitoring or tissue assays. In fact, as our ability to define the population at risk improves, enrollment criteria may change. For example, if we find that exposure modeling is a poor indicator of the absorbed dose for a particular toxic substance, then we should reconsider enrollment criteria based on modeling. This is one way in which the findings of studies on National Registry participants may influence the future membership of the National Registry. In view of the importance of enrollment criteria, they should undergo peer-review prior to their adoption.

H. Data Management

The data management system must be flexible and allow the inclusion of more than one exposure per person and the inclusion of a variety of health related information.

I. Confidentiality

Under the Privacy Act of 1974 (5 U.S.C. Section 552a(e)), employees of Federal agencies are responsible for protecting data collected on identifiable persons or organizations when the supplier of that data has not given consent to the agency to make the data public. This responsibility for protection extends to unauthorized visual observation, accidental loss, or theft. This implies that confidential records should be kept out of sight of unauthorized persons, stored in locked cabinets or locked rooms when not being used, copied only when absolutely necessary, and stored in sealed containers when transferred to archives. Reports of statistics derived from such confidential data should be presented in such a way as to avoid inadvertent disclosure about particular study subjects.

Institutions wishing to conduct health studies and/or surveillance on registrants will have to submit protocols for review which include assurance of confidentiality.

J. Followup

The provision of a satisfactory method of followup is critical to the establishment of a registry. The National Registry will use a hierarchical approach to followup. For those subregistries that are nonparticipatory, nonobtrusive means of followup, such as Post Office change of address cards and vital records, will be used. For subregistries that are participatory, there will be three levels of followup depending on a person's exposure:

1. No followup: those persons who have had either no exposure or an exposure not meeting the enrollment criteria. However, their names will be stored for future reference.

2. Passive followup: those persons who have had minimal exposure. A postcard will be sent to the post office at least yearly to obtain any change of address.

3. Active followup: those persons who have had significant exposure. A postcard will be sent to the post office at least yearly, and when necessary, telephone calls made to the registrant or the person(s) that the registrant named as knowing his/her whereabouts. If neither mail nor telephone contact is able to be made, the National Registry will utilize Internal Revenue Service (IRS), National Death Index (NDI), and Social Security Administration (SSA) records in an effort to locate the registrant. Only after these efforts have proven

unsuccessful will the registrant be listed as lost to followup. Applications for the use of IRS, NDI, or SSA records will be filed by ATSDR for National Registry contractors. It may be necessary to enact legislation similar to that used by Agent Orange Projects in order to access IRS records.

In all of the above, registrants will be encouraged to notify the National Registry of any change of address. This hierarchical approach to followup will provide the ability to contact registrants most likely to need immediate notification or who would be needed as participants in health studies. By not maintaining a high level of effort for all unexposed or minimally exposed registrants, followup costs will be reduced considerably. When needed, a concerted effort can be made to locate all registrants, including a nationwide public education and media campaign.

K. Updating

The registry will be updated as needed, but not less frequently than quarterly, to reflect changes in vital status, new address and telephone number, and the receipt of information from health studies or medical surveillance.

L. Analysis

On a regular basis, the health surveillance and health study data in the National Registry will be analyzed for any indication of previously unrecognized adverse health effects resulting from a toxic substance exposure. The analysis should include but not be limited to frequency distributions, crosstabulations, and trend analysis (seasonal, age, etc). These analyses are specific to the subregistry and should be thought through as each new subregistry is developed. Some of these basic analyses will be done by contract, but the more advanced analyses and their interpretation will be done by the Branch within ATSDR.

M. Reporting

The National Registry will issue a semi-annual report and an annual summary. The report will discuss such items as the number of new registrants enrolled in the reporting period, the names of new subregistries and a brief discussion of the reason for adding them, and the results of the analysis of health surveillance data.

These reports will be provided to the States in which there are subregistries and to other interested parties upon request.

N. Termination

Most subregistries will have finite lifetimes and definite termination rationale that will be specified at their inception. Under certain circumstances a subregistry may be terminated early. Reasons for such an early termination may include:

1. The toxic substance of interest is no longer used or manufactured and all registrants are deceased;

2. Technological advances have enabled the measurement of a previously unmeasurable toxic substance, such as dioxin, in tissue or body fluid. After applying this new technology to persons in the Registry who were originally enrolled on the basis of less precise estimates of exposure, it is found that no one has had a significant exposure to the toxic substance; or

3. A toxic substance is determined through further study to cause no adverse health outcome.

If any of these conditions is met, the subregistry, including followup and updating, should be terminated. When a subregistry is terminated, any surviving registrants should be notified of the termination, the rationale for it, and any implication(s) that it may have for them.

O. Science Advisory Board

ATSDR will establish a Science Advisory Board and will use the Board to provide scientific review of the National Registry's activities. The Board will periodically review all proposed study and health surveillance protocols, as well as the progress of ongoing programs. The Board will advise ATSDR on refinements to the criteria for prioritizing populations for subregistries. The Board will review chemical exposures being considered for subregistries and make recommendations to ATSDR. The Board will be composed of knowledgeable scientists not directly associated with either National Registry activities or the study or health surveillance of registrants.

Decisions regarding the potential notification of registrants to convey medical information or advice will be coordinated with affected State and federal agencies.

IV. SUBREGISTRIES

A. Dioxin

1. Background

In 1971 industrial sludge waste, which originated as a byproduct of hexachlorophene production in a southwest Missouri plant, was mixed with waste oils and sprayed for dust control throughout Missouri. This waste contained approximately 29 kilograms of dioxin*. As a result, almost 250 residential, industrial, and recreational areas are thought to have been contaminated, including the town of Times Beach.

The Centers for Disease Control (CDC) and the Missouri Department of Health (MDH) initially became involved in the investigation of this contamination after receiving a report of a child who had developed hemorrhagic cystitis. In 1974 this work culminated in the laboratory identification of dioxin in the waste oil and soil. With the discovery of widespread dioxin contamination in Missouri in mid-1982, CDC, in consultation with the Missouri Department of Health, resumed public health activities.

As of December 1985, 42 sites, nine of which are in residential areas, have been confirmed as having at least 1 part per billion (ppb) of dioxin in soil; evaluations of additional sites are still in progress. In 1974, levels of 33 parts per million (ppm) were measured in soil at 1 of these 42 sites; in 1985, isolated levels over 1 ppm were found at several sites, but most detectable levels in soil samples ranged from less than 1 ppb to several hundred ppb.

In response to the potential public health problem posed by dioxin contamination in Missouri and other states and the responsibility given to the Agency For Toxic Substances and Disease Registries (ATSDR) by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) to establish and maintain exposure and disease registries, ATSDR asked the Center for Environmental Health (CEH) to convene a Work Group (CEH Work Group) in November 1985 to evaluate the need for a national registry of persons exposed to dioxin. The CEH Work Group's report recommended the establishment of a national registry and the continuation of health studies of persons exposed to dioxin. The report did not recommend health surveillance based on currently available scientific evidence.

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*Dioxin refers here to 2,3,7,8-tetrachlorodibenzo-p-dioxin. Dioxin congeners refers to members of the family of compounds chemically known as the chlorinated dibenzo-p-dioxins.

2. Population Selection

There are approximately 60 sites in the United States known to contain dioxin that would be potentially eligible for the dioxin subregistry of the National Registry. To ensure that there is a potential for exposure, EPA environmental sampling data will be reviewed to identify sites that have dioxin levels of 1 ppb in soil.

The chlorinated dibenzo-p-dioxins comprise a group of 75 chemical congeners, produced as waste by-products during the manufacture of various phenolic compounds (e.g., 2,4,5-trichlorophenol). Of these congeners, dioxin has been most extensively studied and is considered to be the most toxic. Animal toxicity studies have shown that the organ systems most prominently affected are the liver (acute toxicity and hepatocarcinogenesis), the immune system (thymic atrophy and decreased cell-mediated immunity), the skin (chloracne-like changes), and the reproductive system.

Most of our direct knowledge of the effects of dioxin exposure on human health has been obtained from the study of workers exposed to dioxin during the production or subsequent handling of 2,4,5-trichlorophenol or pesticides produced therefrom, such as 2,4,5-trichlorophenoxyacetic acid. In some occupationally exposed workers chloracne, but no systemic illnesses, has developed. Authors have reported weight loss, easy fatigability, myalgias, insomnia, irritability, and decreased libido in exposed workers. Reports of liver enlargement and tenderness and neuro-sensory changes, particularly in the lower extremities, have appeared. Total serum lipids may be increased, and the prothrombin time may be prolonged. Porphyria cutanea tarda (PCT), an acquired form of porphyria characterized by chronic skin lesions, has also been observed. More recent reports have associated dioxin exposure with abnormal immune function, though no clinical illness was noted. The most specific findings are chloracne (which can also be caused by other structurally related compounds such as polychlorinated biphenyls [PCBs] and chlorinated naphthalenes) and PCT (which also has a variety of potential causes).

Therefore, dioxin is suspected to cause a variety of adverse health outcomes both permanent and reversible. Efforts are underway in epidemiologic and laboratory research to elaborate the effects of dioxin on human health.

3. Population Identification

Once sites with the potential for exposure are identified, the following enrollment criteria will be applied: Any person with either (1) an effective body dose of or (2) an environmental exposure to dioxin or dioxin congeners equivalent to or exceeding the dose estimated to produce an excess cancer risk of one per million persons per 70-year lifetime will be eligible to enroll in the dioxin subregistry of the National Registry. The dose range* estimated to produce this excess risk of cancer is 0.7 to 36 nanograms per kilogram, assuming that the dose rate has no effect on carcinogenicity.

After the sites with dioxin levels high enough to potentially expose individuals to the above dose have been identified, the individuals that were potentially exposed at these sites will be identified.

4. Exposure and Enrollment Criteria

Based on the dose range stated above, it is estimated that a person exposed for 3.2 to 175 years to Missouri residential soil contaminated with dioxin at a level of 1 ppb will acquire an excess lifetime cancer risk of one in a million. To be conservative, individuals who have lived in areas with soil contamination of 1 ppb for one year will be eligible to enroll in the National Exposure Registry.

For other settings and types of exposure, separate risk estimates will be developed to establish site-specific enrollment criteria for the dioxin subregistry of the National Registry. For example, if persons have eaten fish contaminated with dioxin, health officials will have to estimate exposure to dioxin from information on the concentration of dioxin in the fish, the amount of fish eaten, and the absorption of dioxin from the ingested fish. If the absorbed dose is equivalent to or exceeded the dose cited above, then the fish-eaters would be eligible to enroll in the National Registry.

5. Type of Subregistry

This subregistry will be participatory. Each individual potentially exposed to dioxin will be contacted and a questionnaire administered after receiving informed consent. This information will be used to determine eligibility, by identifying individuals who have lived in an area contaminated with 1 ppb dioxin for at least one year.

Core data items, data management, followup, updating, analysis, reporting, and termination will follow the guidelines general methods described in Section III.

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*This enrollment criterion is based on the risk estimates developed in "Health Implications of 2,3,7,8-tetrachloro-dibenzodioxin (TCDD) Contamination of Residential Soil" by Renate D. Kimbrough, Henry Falk, and Paul Stehr, which was published in the Journal of Toxicology and Environmental Health, 14:47-93, 1984.

B. Beta-naphthylamine

1. Background

The Drake Chemical Company (formerly Kilsdonsk Chemical Corporation) and its neighbor, American Color and Chemical Corporation (ACC), are located on a 46 acre site in the vicinity of Myrtle Street in Lock Haven, Clinton County, Pennsylvania. The Kilsdonsk Chemical Corporation operated at this site from about 1948 to 1962, at which time Drake Chemical assumed ownership. Drake continued the operation until its bankruptcy in August 1981.

There has been a great deal of concern about this chemical manufacturing site because of potential occupational exposure of its employees to beta-naphthylamine (BNA), a well-known human bladder carcinogen. Kilsdonsk produced BNA, which was used by ACC to make dyes. In 1961 the manufacture, use, and storage of BNA was outlawed in Pennsylvania; however, small amounts of BNA may have been synthesized at Drake subsequent to 1961 during the production of Broenner's acid. The plant site has been designated a Superfund site by the Environmental Protection Agency, thereby making its cleanup funded by Superfund.

2. Population Selection

There are approximately six other plants in the United States that manufactured BNA that would be potentially eligible for the BNA subregistry of the National Registry. To ensure that there is a potential for exposure, industrial hygiene data as well as historical information will be reviewed.

Long term occupational exposure to BNA is associated with an increased incidence of inflammation of the bladder and/or bladder cancer. The major route of exposure is inhalation or direct contact. In fact, BNA is among the most potent chemical carcinogens. The risk for BNA induced bladder cancer extends for decades after the exposure. The average interval from onset of first BNA exposure to the development of bladder cancer is 20 years, but this may range to 40 years.

Therefore, BNA is a known carcinogen. Early detection and treatment of bladder cancer can decrease morbidity and increase years of life in affected individuals.

3. Population Identification

Any plant where BNA was manufactured will be eligible to become part of the BNA subregistry. Besides Drake there are approximately six other plants in the United States that manufactured BNA. If workers from these plants are considered for inclusion in the National Registry, enrollment criteria comparable to those for Drake Chemical will be sufficient to confer eligibility.

After the sites that are eligible to enroll have been identified, the individuals potentially exposed will be identified using employment records.

4. Exposure and Enrollment Criteria

Any person who worked at either the Drake (Kilsdonsk) or American Color and Chemical plant during 1940-1981, inclusive, will be eligible to enroll in the BNA subregistry of the National Registry. Although there is no industrial hygiene data from Drake, historical information, including photographs, shows that the contamination was so heavy that it was visible to the naked eye. Thus, it is likely that anyone who worked at the Drake Site was exposed to BNA. Researchers estimate that 370 former employees are still alive who were exposed to BNA at the Drake Site between 1940 and 1981.

5. Type of Subregistry

This subregistry will be participatory. Each individual potentially exposed to BNA will be contacted and a questionnaire administered after receiving informed consent. Bladder cytology screening for diagnosis of bladder cancer will be available for members of the subregistry.

Core data items, data management, followup, updating, analysis, reporting, and termination will follow the guidelines described in Section III.

Working Draft
January 1987

V. ISSUES

There are many ways to establish and maintain a registry of persons exposed to toxic substances. Following is a list of issues by category that will be discussed as part of the National Workshop:

A. Ethical Issues

1. participatory vs nonparticipatory
   (can individuals be followed without their knowledge?)

2. confidentiality
   (who should have access to registry information?)

3. long-term funding
   (how to assure long-term funding when CERCLA must be reauthorized every five years?)

4. access to information by others
   (submission of protocol for review)

B. Chemicals

1. definitions of exposure
   (each population/chemical must have its exposure criteria)

2. levels of exposure
   (what level of exposure should be registered and followed?)

3. factors determining next populations for subregistries
   (refinement of criteria for population selection outlined in the proposal)

C. Research

1. criteria to be used for access to information
   (scientifically valid, burden to respondents, likelihood of being able to provide meaningful information to respondents)

2. mechanism for access to registrants
   (submission of protocol for review)

3. what types of research
   (using registry for sampling frame, analysis of existing data in registry, etc.)

Working Draft
January 1987

D. Health Surveillance

1. types of diseases
(diseases for which early detection and treatment will affect outcome)

2. types of programs
(biologic monitoring, questionnaires, etc.)

3. mechanism for doing surveillance and reporting findings to registrants and registry
(testing done centrally or locally, reports to the individual or his/her physician)

E. Operational Issues

1. types and degree of followup
(three levels of followup proposed according to level of exposure)

2. how to get out of a subregistry
(when individuals no longer wish to be a part of a registry how do they notify ATSDR?)

3. ending a subregistry's maintenance
(specific termination rationale have been outlined in the proposal)

4. how to deal with deaths
(information of cause of death should be collected on registrants)

5. cost containment
(three levels of followup will lower costs associated with this function; should other possibilities be explored?)

6. how often should subregistry be updated
(a subregistry should be updated not less than quarterly)

F. Notification

1. how to communicate new findings?
(letter to the participants and/or their physicians, notice in news media, etc.)

2. what findings should be communicated?
(all - some?)

3. liability
(what information do participants legally have to have?)

4. who does the notification of new findings?
(ATSDR - researchers?)

Senator METZENBAUM. Thank you very much, Senator Quayle.

I want to say thanks to each of the members of this panel and to all of the others who have participated. This will not be the final hearing in connection with this matter. As Senator Quayle has indicated, there will be another hearing on March 9th.

We stand adjourned.

[Whereupon, at 12:35 p.m., the subcommittee was adjourned.]

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